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# MEASURING THE HEALTH- RELATED QUALITY OF LIFE OF WOMEN USING CONTRACEPTION: A SYSTEMATIC REVIEW AND ANALYSIS OF AVAILABLE TOOLS

**Institute for Women's Health**

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## Abstract

**Background:** This was a study with the primary aim of ascertaining what the best way is to measure the health-related quality of life (HRQOL) of women using contraception. A systematic literature review was conducted to (a) identify which, if any, outcome measures exist that assess the contraception specific quality of life (QoL) of women of a reproductive age and (b) to identify which other HRQOL measures are being used in place of a contraception-specific HRQOL questionnaire and to assess whether they are fit for purpose. Secondary aims were to (c) assess what women think about the questionnaires that have been specifically made to measure HRQOL of women on contraception and (d) suggest recommendations for future work in this field.

**Materials and Methods:** The online search engines Medline, Embase, PsycINFO and CRD database (DARE and NHSEED) were explored, using three broad search terms: (contraception) AND (quality of life) AND (outcome measure), to identify suitable papers for the study. Secondly, preliminary pre-testing was done to establish what women of a reproductive age thought about the ORTHO BC-SAT questionnaire, designed specifically to assess women's satisfaction with their contraception. Thirdly, analysis of two of the contraception specific questionnaires (ORTHO BC-SAT and SEC-QOL) was performed using the COSMIN checklist (COnsensus-based Standards for the selection of health status Measurement INstruments) and Ferrans model for HRQOL.

**Results:** Of 11,198 titles yielded from the search, 111 studies met the inclusion criteria. Within these studies, 59 validated HRQOL questionnaires were identified. The most commonly used questionnaire was the Short Form 36 (SF-36)(17.6%), followed by the Moos Menstrual Distress Questionnaire (MDQ)(10.6%). Four contraception specific questionnaires were identified, namely the ORTHO birth control satisfaction assessment tool (ORTHO BC-SAT), the Spanish contraception society QOL (SEC-QOL) tool, The EVAPIL Scale and The NuvaRing Acceptability Questionnaire.

**Conclusion:** This study concludes that it is not appropriate to use a generic HRQOL questionnaire to measure the QoL of women, specific to contraceptive use. The SF-36 and the EQ-5D are too generic and do not cover essential areas such as sexual function and satisfaction and menstrual and pre-menstrual symptoms. The ORTHO BC-SAT is a good measure of satisfaction of women with their contraception but it lacks adequate questioning on sexuality, it's long and sometimes repetitive. The SEC-QOL needs further research on a British population to be used in the UK. There is a need for a need specific HRQOL questionnaire, designed for the purpose of assessing HRQOL in women using contraception. This questionnaire should follow Ferrans and colleagues model for HRQOL research and should include relevant questions on menstrual symptoms, mental health and sexuality.

## 1.0 Introduction

This section will explore the relevant background literature with regards to what quality of life means, how we measure it and why it is important. It will also explore relevant literature on quality of life measures, particularly those designed to assess sexuality and the importance of this in relation to contraception. The advantages and disadvantages of contraception will then be considered before further exploring their relative impact on the health-related quality of life of women. A brief overview of health economics and its application to contraceptive use will be studied. Finally, this section will explain the gaps in research and the aims and objectives of this project.

### 1.1 *Health-Related Quality of Life*

Quality of life (QoL) is an interesting concept and one that is difficult to define. Health-Related quality of life (HRQOL) is the QoL relative to health or disease status. HRQOL is subjective; Calman hypothesised that quality of life is only achieved if a person's expectations are met by their experience<sup>1</sup> and as such, QoL or HRQOL can only really be defined by patients themselves, as we all have different expectations from life. HRQOL is also dynamic; it will fluctuate depending on current state and experience. Finally, it is multidimensional; the dimensions associated with HRQOL are typically physical, social, psychological and spiritual factors.<sup>2</sup> A HRQOL questionnaire is a type of Patient Reported Outcome (PRO) Measure. A PRO is a measure of any aspect of a patient's life, as reported by them.<sup>3</sup>

HRQOL can be affected by both intrinsic and extrinsic factors. Contraception is an example of an extrinsic factor that can have both negative and positive effects on HRQOL and this paper will explore the ways in which it does so. It will consider how these changes are perceived by women and how fear of perceived side effects can also influence decision making with regards to contraception. It will then consider whether it is important to measure this change in HRQOL and if so, how best to do it.

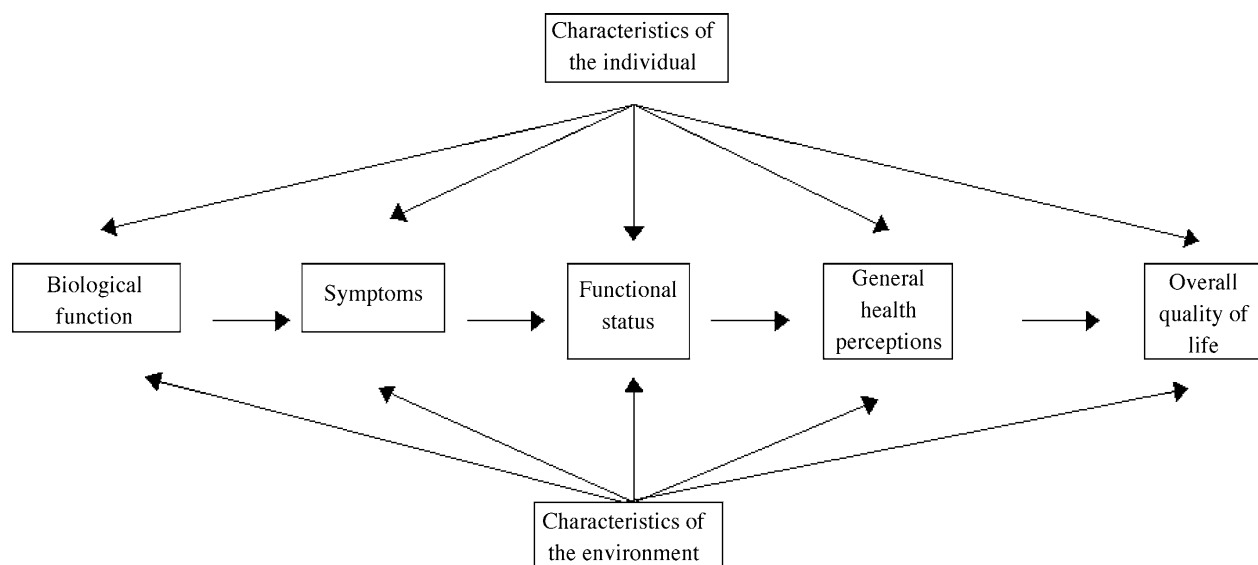
### 1.2 *How We Measure Quality of Life and What to Measure*

In healthcare, HRQOL questionnaires are used as a tool to quantify QoL relative to health, by asking a series of questions and evaluating a person's satisfaction within different areas of their lives. HRQOL questionnaires are designed to compare the impact of one intervention to another.<sup>4</sup> The field of HRQOL measures has been advancing over the last four decades. It is a formal discipline that combines prescribed theory and discrete methods.

There are three common models that should be considered when carrying out HRQOL research – Wilson and Cleary, Ferrans and Colleagues or the World Health Organization (WHO) model.<sup>2</sup> By using common language and by suggesting HRQOL domains to follow, these models allow easy comparison across studies and provide structure to the concept of HRQOL. Bakas et al., suggest that Ferrans and colleagues' model has the greatest potential for the future. It is an improvement on Wilson and Cleary as they have added 'individual' and 'environmental' factors to the model.<sup>5</sup> 'Characteristics of the *individual*' includes demographic, developmental, psychological and



biological factors that have an effect on outcome. This information is useful to know when targeting groups to screen, for example, high risk groups for heart disease. 'Characteristics of the *environment*' are categorised into social or physical. Social includes influences such as family, friends and healthcare providers and physical refers to the environment in which they live and work. This information is useful when assessing a specific cultural group, for example. By adding these two factors to the model, Ferrans et al., have allowed for better comparison across studies using this model. The figure below summarises Ferrans and Collaegues' model for HRQOL (the revised Wilson and Cleary model). It focuses on the five types of measures of patient outcomes: (a) *biological functions*, such as physiological changes, measured by laboratory tests, (b) *symptoms*; physical, emotional and cognitive, (c) *functional status*; physical, psychological and social function (d) *general health perceptions* which is the subjective ratings of all previous domains and (e) *overall QoL*; how happy is the person with their overall QoL?<sup>5</sup>



**Fig. 1** Revised Wilson and Cleary model for health-related quality of life. Taken from Ferrans et al., 2005

Many tools exist, across various different specialties, to assess patient's QoL. The list of tools available is extensive. Many tools are generic and are designed to cover the broad 'domains' of mobility, self-care, limitations on activity, pain and psychological well-being. Examples of such are the Short Form-36 (SF-36)<sup>6</sup> and the EuroQol instrument (EQ-5D).<sup>7</sup> These will both be discussed in detail later. Other well-known tools, used to assess psychological well-being associated with various conditions, are the Beck depression inventory<sup>8</sup> and the Psychological General Well Being Index (PGWBI).<sup>9</sup> Many more exist, such as the WHOQoL-BREF, a generic measure designed to assess HRQOL cross-culturally<sup>10</sup> and the Women's Health Questionnaire (WHQ), designed to assess the physical and mental health of mid-age women.<sup>11</sup>

The focus of this paper is to assess the measurement of the HRQOL of women using contraception. The aforementioned domains are broad and do not translate well into the realms

of contraceptive use. Although contraception can have an effect on all of these domains, it is not sufficient to ask such broad questions that bear greater relevance to chronic illness or disease.<sup>7</sup> The effects that we want to measure when thinking about contraceptive use are those such as breast tenderness, pelvic pain, menstrual bleeding and mood changes, as well as sexual function. Although all of these symptoms can in turn affect the broader domains mentioned, a more specific assessment is needed. For example, we need to assess sexual satisfaction or sexual QoL (SQoL), which does not feature in the most commonly used questionnaires. This is a shortfall, as we know there is a positive correlation between sexual satisfaction, better health and improved QoL.<sup>12, 13</sup> Furthermore, chronic illness and mental health have sizable negative effects on sexual function, and as such, they should be addressed and assessed regardless.

There are, however, a few HRQOL questionnaires that do specifically measure SQoL. Though, these alone would not be suitable to capture the entire effect of contraception on QoL either. The Female Sexual Function Index (FSFI) is a 19-item self-report questionnaire which assesses six domains; desire, arousal, lubrication, orgasm, satisfaction and pain.<sup>14</sup> It uses a 5-point scale to answer questions such as “Over the past 4 weeks, how often did you feel sexual desire or interest?” from almost always to almost never. Another question that could be particularly relevant to the effects of contraception is “Over the past 4 weeks, how often did you become lubricated (‘wet’) during sexual activity or intercourse?” (Appendix). These questions are applicable as we know that lubrication and libido can both be affected by contraceptive use.<sup>15, 16</sup> So although contraception can have a profound effect on sexuality (either positively or negatively) and as such, all 19 of the questions are relevant to contraceptive use, changes in sexuality are not the only effects of contraception and so this measure alone would not be suitable for our purpose. The Sexual Quality of Life Female (SQOL-F) questionnaire is another measure of sexual function. It uses 18 items with a 6-point scale and focuses on sexual self-esteem and emotional and relationship issues.<sup>17</sup> It asks the user to rate their feelings on questions such as “When I think about my sexual life, it is an enjoyable part of my life overall” or “When I think about my sexual life, I am embarrassed”, or I feel “frustrated”, “depressed”, “anxious”, “angry”, “guilty”, “good about myself”, “less like a woman”.<sup>18</sup> Similarly, there is the Sexual Activity Questionnaire (SAQ), originally designed to investigate the impact of tamoxifen on sexual function in breast cancer patients. It asks the participant questions on their sexual desire, frequency and satisfaction and if they experience vaginal dryness or pain on penetration.<sup>19</sup> So, whilst none of these questionnaires were specifically designed with contraception use in mind, questions about sexual dysfunction, activity and satisfaction are extremely important and should be included in a questionnaire to assess QoL related to contraception. Therefore, sexuality should be considered when evaluating the suitability of any measures found to assess the QoL of women of contraception.

### *1.3 Health Economics – What is a QALY?*

As health budgets are finite, it is the role of a health economist to determine how best to allocate limited resources. Health economists use economic evaluations to measure health outcomes in one of five ways: cost-consequence analysis, cost-benefit analysis, cost-effectiveness analysis and cost-utility analysis<sup>20</sup> or most commonly, quality adjusted life years (QALY).<sup>21</sup> QALYs measure

disease burden and allow us to compare interventions and assess their economic benefit. They are measured between 0 and 1, with a score of 1 equating to a year in perfect health.<sup>22</sup> Time based preference measures should be included to allow the decision maker to weigh up what is more important to the individual filling in the questionnaire.<sup>23</sup>

HRQOL questionnaires play an important role in determining the economic benefits of any given treatment and can be used to generate QALYS. In the UK, QALYs are then used by the National Institute for Health and Care Excellence (NICE) to help allocate funding for the intervention in question.<sup>24</sup> QALYs measure the impact of a treatment on a person's HRQOL as well as the length of life. This is relevant to contraception, because despite being so widely used, discontinuation rates are high and a poor understanding of the side effects can lead to non-compliance. Non-compliance in-turn can lead to unintended pregnancies, making the economic benefit of the contraception redundant. The cost effectiveness of contraception is based on the balance of the benefits, the harms and the associated cost with either the contraception (the cost of the product itself, appointment time to the service, insertion, removal, counselling, management of symptoms) or the outcomes of unintended pregnancies (birth, abortion, miscarriage or ectopic pregnancy), as well as any intangible costs.<sup>21</sup>

By using a HRQOL tool that is designed for the specific use of measuring the HRQOL of women using contraception, we may be able to improve compliance and uptake, reduce unintended pregnancy rates and reduce costs to the NHS. Such a tool would be useful in comparing different forms of contraception in different groups of women or changes in HRQOL in the same group of women over time. By assessing women's satisfaction with a type of contraception we can add to research in this area and help aid commissioning choices.

## 1.4 Contraception

### 1.4.1 Importance of Contraception

According to the United Nations (UN), in 2015 the mean global percentage of married women or women in union that are of reproductive age and using some form of contraception was 64%, an increase from 62.7% in 2009.<sup>25</sup> Contraception is playing an increasingly important role in the lives of women worldwide. It is predicted that 272,040 maternal deaths were averted in 2008 by contraceptive use, and, by satisfying the unmet need for contraception, a further 104,000 maternal deaths could be avoided in the future (a 29% reduction).<sup>26</sup> Contraceptive use is not only lifesaving; it also has the potential to enhance the QoL of women by protecting reproductive autonomy and allowing women to plan their lives and careers as they wish. As such, it is important to know the effect that contraception is having on the female population – both the positive and negative. Ultimately, the more satisfied a woman is with her contraception, the more likely she is to continue to use it.

### 1.4.2 Side Effects of Contraception

We are now able to offer women many forms of contraception; there are various pills with differing levels of hormones, injections, patches, hormonal and non-hormonal intrauterine devices, vaginal rings and various barrier methods. The side effect profile of each of these

methods is different and is individual to each woman. The positive and negative effects of the most commonly used methods is discussed below.

The combined oral contraceptive pill (COCP) is the most widely used method of reversible contraception in developed countries.<sup>25</sup> There are many different COCPs available which all contain varying types and amounts of an oestrogen and a progestogen, which are taken for 21 days, followed by a 7-day pill-free interval.<sup>27</sup> Fear of perceived side effects play a large part in COCP discontinuation. A systematic review of 28 studies evaluated negative attitudes towards oral contraceptives<sup>28</sup> and identified an overwhelming amount of fear of the contraceptive pill. In one European study, 27% of never-users in a European study quoted 'side effects' as the reason for not taking the pill, despite having never tried it.<sup>29</sup> Weight gain is another major reason for discontinuation of the COCP, with several studies citing it as the primary reason for cessation (up to 20%). However, a Cochrane review found that there is no causal association between weight gain and the COCP.<sup>30</sup> Evidently, in some instances, conflicting evidence may be contributing to women's fears about contraception. The COCP can also have a profound effect on sexuality;<sup>15</sup> it causes a reduction in androgen levels which can lead to vaginal dryness and reduced libido.<sup>13</sup> Other common side effects include headaches, nausea, erratic bleeding, oedema breast tenderness and mood changes,<sup>31,32</sup> although yet again, a separate study has shown that these symptoms are no different in a control group.<sup>33</sup>

Positive effects of the COCP include improved cycle control, relief of menstrual symptoms, improved acne and hirsutism and, in women over forty, preserved bone mineral density. The COCP also has a protective effect against ovarian, endometrial and colorectal cancer<sup>31</sup>. As discussed, there is a lot of conflicting information in the literature about the side-effects of contraception.

The progesterone only pill (POP), also known as the 'mini-pill', is a pill taken every day, which is 99% effective if taken correctly. It can be used in women who are unable to take oestrogen, for example, due to heart conditions, risk of blood clots or smokers over 35.<sup>34</sup> It has been shown to make periods lighter and less painful. It is also an effective treatment for women who suffer with migraines.<sup>35</sup> Negative effects of the POP include acne, breast tenderness, nausea and vomiting, ovarian cysts and weight gain.<sup>36</sup>

The intrauterine system (IUS) is a small 'T-shaped' device that is inserted into the uterus. It releases a progestin (levonorgestrel) locally and prevents pregnancy by thickening the cervical mucus, thinning the endometrial lining and by sometimes preventing ovulation.<sup>37</sup> The two most common brands of the levonorgestrel intrauterine system (LNG-IUS) in the UK are the Mirena coil or the Jaydess. There is evidence that the LNG-IUS is an effective treatment for endometrial hyperplasia<sup>38</sup> and can also be used to treat women who suffer from heavy menstrual bleeding (HMB).<sup>39</sup> An intrauterine device (IUD) is a small 'T-shaped' device that is inserted in the same way as the IUS but differs in the fact that it does not contain any hormones and is instead made of copper, which acts as a spermicide, thus preventing fertilisation.<sup>40</sup>

The main side effects of both the IUD and IUS are pain and bleeding.<sup>40, 41</sup> In a study of over 2,500 women using either the IUD or the IUS, the discontinuation rate at 12 months was 23% for the copper IUD and 18% for the LNG-IUS. The two main reported reasons for discontinuation were pain (31%) and bleeding (24%). However, these side effects have been shown to decrease over time<sup>40</sup> and this should be used to counsel and reassure women who are considering removal of device. In the same study, failure rates, defined as the percentage likelihood of achieving pregnancy, at 12 months were 1.3% and 0.2% respectively<sup>42</sup> and the expulsion rate of the copper IUD was 6%, compared with 3% in the LNG-IUS at 12 months and. Expulsion of the copper IUD has been shown to be higher in women aged 14-19, regardless of their parity.<sup>43</sup> However, especially for nulliparous women, pain and excessive bleeding can often lead to intolerability and subsequent removal.<sup>44</sup>

Benefits of the IUD include not having to attend regular appointments or worry about remembering to take a pill every day and it can remain in situ and last for up to ten years. This makes it beneficial for rural, underdeveloped communities across the world. Furthermore, the IUD is an effective form of emergency contraception following unprotected sex<sup>45</sup>. The copper IUD is also beneficial for women who suffer from the hormonal side effects of other methods, or for those who have contraindications according to the UK Medical Eligibility Criteria for Contraceptive use (UKMEC).<sup>34</sup>

The implant (Implanon®) is a small 40mm rod that is inserted subdermally into the arm. It works by continuously releasing progestin and has an efficacy rate of 99%.<sup>46</sup> A study that looked at the acceptability of nearly 1000 women using the Implanon implant found that headaches were the most commonly reported side effect (15.3%).<sup>47</sup> The overall discontinuation rate was 32.7%, with 10.4% requesting removal due to bleeding irregularities. In another study, 41.25% of women reported amenorrhoea, 23.75% reported infrequent bleeding and 17.5% reported frequent bleeding.<sup>46</sup> Others reported breast tenderness, acne, headaches, dizziness, depressive mood disorders, pelvic pain and loss of libido.<sup>46</sup> Other side effects of the implant include mood changes, weight gain, pain at site of insertion and anaemia.<sup>48</sup> Benefits include not having to worry about contraception for three years and in some cases lighter bleeding. It is also suitable for people who are not able to have oestrogen contraception for reasons outlined by the UKMEC.<sup>34</sup>

The depot-medroxyprogesterone acetate (DMPA) injection (Depo-Provera) is a 12-weekly progesterone injection which prevents pregnancy by thickening cervical mucus and thinning the endometrial lining. Its use has been shown to decrease the risk of endometrial cancer, ectopic pregnancy, menorrhagia, dysmenorrhoea and premenstrual symptoms, amongst other benefits.<sup>49</sup> Reported side effects include headaches, acne, breast tenderness, mood changes and loss of libido. However, the most well-reported side effect of the DMPA is weight gain. One study that compared the use of DMPA to the LNG-IUS showed that the DMPA users put on an average of 4.3kg over 5 years, compared to 1.8kg in the LNG-IUS group.<sup>50</sup> Benefits of the DMPA include its protective effect against endometriosis and its use in controlling sickle cell crises.<sup>51</sup>

### 1.5 Gaps in Research

The Contraception Choices Project (formerly the BeCCy Project) is a programme at University College London led by Professor Judith Stephenson and Dr Julia Bailey. The aim of which is to produce a website to assist women in making choices about contraception. It will address concerns and misconceptions and recommend contraception based on a woman's needs and preferences. Health economist Rachael Hunter was working on the project and identified the need for a specific contraception HRQOL measure including economic evaluations of interventions related to contraception. The EQ-5D was initially considered for use in the project; however, it was deemed neither relevant nor specific to contraception. The SQuoL-F was subsequently considered but as this focuses mainly on sexual dysfunction, it was also deemed unsuitable. Thus, it became evident that there is a need for a suitable measure specific to contraception and its effect on QoL. From a preliminary search, there did not appear to be a useful or suitable tool to assess the impact of the effects of contraception on QoL. As such, it became necessary to perform a systematic literature search to find a suitable tool or to highlight the gap in this area.

### 1.6 Aims and Objectives

The overall aim of this project was to ascertain what the best way is to measure the QoL of women using contraception. This was addressed using three main research questions:

1. *Which, if any, outcome measures exist that assess the contraception specific health-related quality of life (HRQOL) of reproductive women?*
2. *What do women think about the questionnaires that have been specifically made to measure HRQOL of women on contraception?*
3. *Which other HRQOL measures are being used in place of a contraception-specific questionnaire and are these fit for purpose?*

These questions will be addressed by:

- a) Completing a comprehensive systematic review of the literature to find what tools are in circulation.
- b) Undertaking preliminary pretesting using the ORTHO birth control satisfaction tool (ORTHO BC-SAT) by asking women of reproductive age to fill in the contraception specific questionnaire and to give feedback on its suitability.
- c) Analysis of any specific instruments found using the COSMIN checklist (CONsensus-based Standards for the selection of health status Measurement INSTRuments) and by comparing them to Ferrans and colleagues' model.
- d) Analysis of generic HRQOL instruments used in place of contraception specific instruments to judge whether they are fit for purpose.

Following this work, a conclusion will be reached with regards to whether it is necessary to have a contraception specific HRQOL instrument or if it is suitable to use something generic such as the SF-36 or the EQ-5D. Recommendations will be given about what questions should be asked in future developments of such a questionnaire.

## 2.0 Methods and Materials

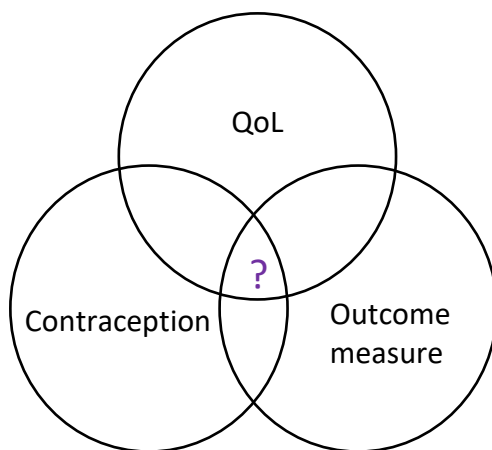
This chapter will outline the three main sections to the work: the literature review, the HRQOL questionnaire analysis and the preliminary pretesting research. The ways in which the protocol was designed and the inclusion and exclusion criteria of the literature search will be given. The Scientific Advisory Committee (SAC) criteria for HRQOL questionnaire analysis and the COSMIN checklist will be explained and the preliminary pretesting process will be presented.

### 2.1 Literature Review

The systematic review protocol, inclusion and exclusion criteria and the data selection process were designed using PRISMA (preferred reporting items for systematic review and meta-analyses).

#### 2.1.1 Search Strategy

An extensive search was performed on Medline, Embase, PsycINFO and CRD database (DARE and NHSEED). The three broad search terms used were (contraception) AND (quality of life) AND (outcome measure) (Fig 1.). The full search protocol can be found in the appendix.



**Fig 2.** Venn diagram to illustrate search terms used and area of interest, marked with a ‘?’.

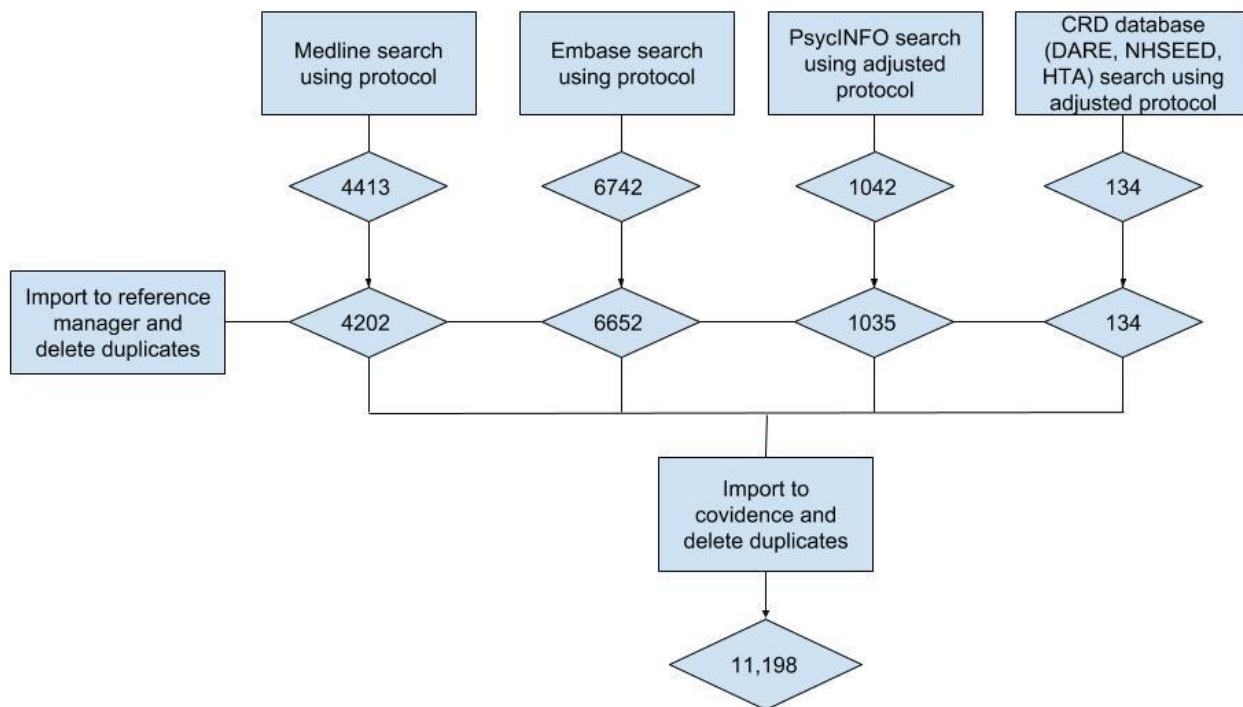
Within contraception, terms for all the different forms of contraception were used, including hormonal and non-hormonal. Terms for induced abortion and unplanned pregnancy were also included as it was thought that some interesting questionnaires may exist that overlap with contraception use/non-use. Within quality of life (QoL), terms were used to include patient satisfaction, relationship satisfaction and emotions. Various search terms for ways of assessing the QoL were included, such as questionnaire and survey (Appendix). The search was limited to human studies only but no time limit was applied, nor a language criterion, provided there was an English translation.

### 2.1.2 Inclusion Criteria

All studies that used a validated or self-developed questionnaire to assess quality of life, overall satisfaction, mental health or affect were initially included. The women in the study could be taking contraception for any purpose; it does not have to be for contraceptive purposes (e.g a teenager taking Dianette for acne or a woman using an intrauterine device for heavy menstrual bleeding). Studies of women of reproductive age were selected through screening. To be included initially, studies needed to ask detailed or structured questions about the side effects, QoL, satisfaction or overall wellbeing of women who are using any form of contraception. This could be through an interview or a questionnaire.

### 2.1.3 Exclusion Criteria

Studies that assess menopausal women were excluded through screening. Much is already known about quality of life in the menopause and there are many established questionnaires that assess this. Male studies were also excluded at screening but not in the original search strategy as there may be some studies that included males and females in assessing quality of life with contraceptive use. Animal studies were excluded through the search strategy. Grey (unpublished) literature was not searched, nor were trials registers.



**Fig 3.** Flow chart to demonstrate the number of articles retrieved from each database and the final number of articles to screen following removal of duplicates (11,198).



#### *2.1.4 Data Extraction*

The four databases were searched using University College London library databases and the University of York Centre for Reviews and Dissemination website. The search strategy was altered to suit the different databases. All references were exported into Mendeley reference manager and screened for duplicates. They were then imported into Covidence website online and screened again for duplicates. This yielded 11,198 papers (**Fig.2**)

##### *2.1.4.1 Title and Abstract Screening*

All 11,198 titles and abstracts were read by the first author and 10% of these were screened by a second researcher for quality control. Papers were moved to full text screening if the paper was relevant and met the inclusion criteria. Papers that were not suitable were excluded and papers that were vague in their abstract or had a suitable title but no abstract, were marked as 'maybe', which moved them onto full text screening for a more thorough screen. Of the 1,200 papers that were screened by the second reviewer, 37 decisions conflicted with the first author. These were discussed and an overall decision was agreed on between the two researchers. In total, 740 articles were advanced to the full text screening stage.

##### *2.1.4.2 Second Round Screening*

At this stage, due to the large amount of papers through to full text screening, a second round of title and abstract screening was employed. A slightly stricter criteria was applied; to include only those studies that use a validated questionnaire, or a structured, self-developed questionnaire. At this stage, studies that had previously been included for simply asking satisfaction on a Likert scale, were excluded. Similarly, if a study simply explored side effects of the contraception or menstruation but did not quantify this by means of a questionnaire, they were also excluded. Papers that focused exclusively on the sexual QoL of women on contraception were also excluded, as although sexuality is a very important part of QoL, it is not the sole focus. Ultimately the papers had to fit into one of two groups:

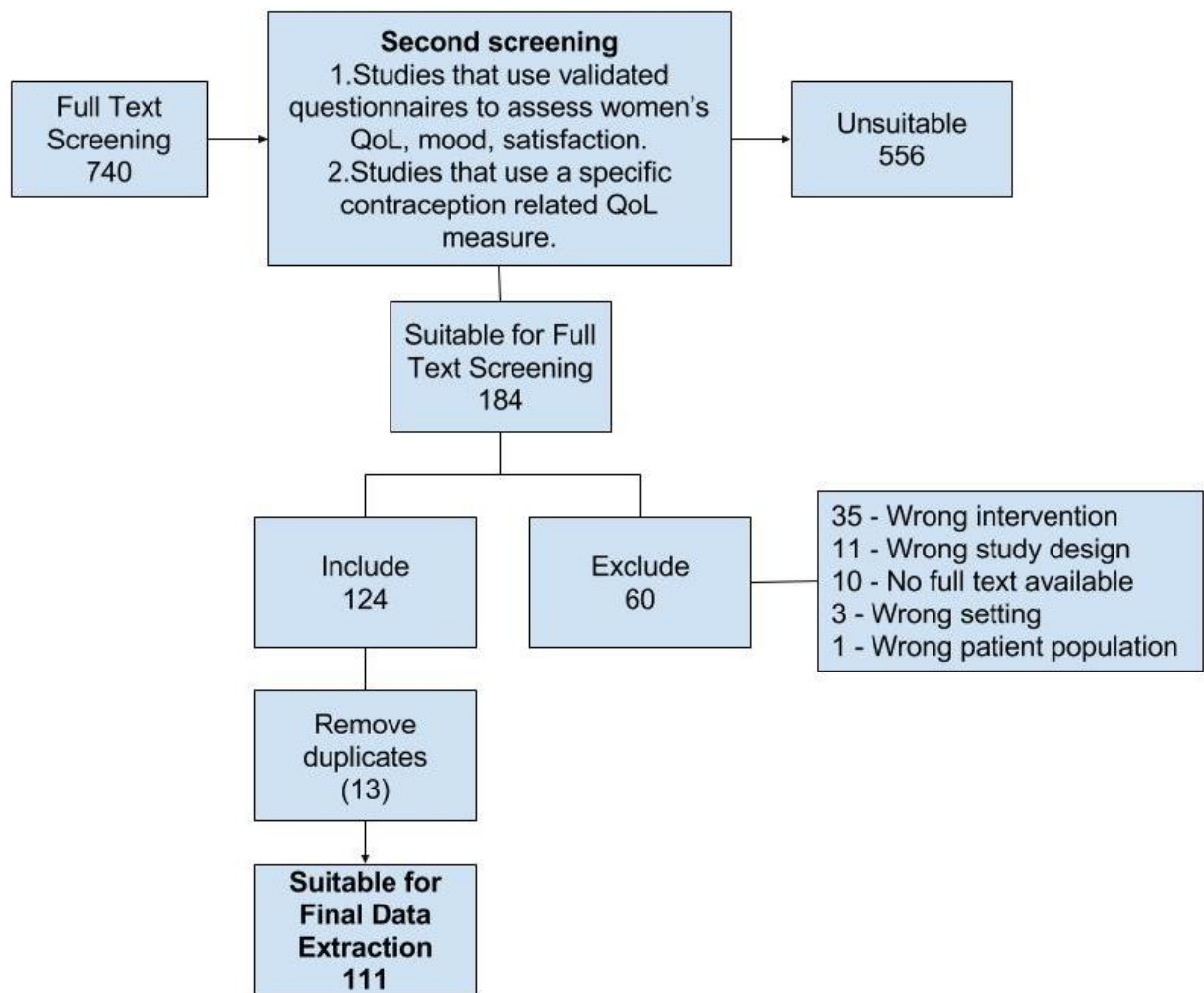
1. Studies that use validated questionnaires to assess women's QoL, mood, satisfaction. This included tools such as the SF-36 or the Beck's depression Inventory.
2. Studies that use a specific contraception related QoL measure.

Following this, a further 556 papers were excluded, leaving 184 papers suitable for full text screening.

##### *2.1.4.3 Full Text Screening*

Ovid or Google Scholar were used to obtain the full text of articles where possible. If the full text was not available and the abstract did not allude to any suitable questionnaire, then the paper was excluded. Similarly, if the information could not be gained from the abstract, and an English version of the full text was not available, then they were also excluded.

There were a further 60 studies excluded at this stage. Thirty-five were excluded as they were the 'wrong intervention'. This meant they were excluded if the questionnaire used didn't answer the research question, i.e if the study did not use a validated measure to assess QoL. Studies were also excluded here if they were using a very specific questionnaire such as the MIDAS (migraine



**Fig 4.** Flowchart showing methodology for second round screening. 111 articles suitable for final data extraction.

disability assessment) questionnaire. Eleven studies were excluded under ‘wrong study design’ if they did not actually use a HRQOL measure at all, when the full text was screened. Ten were excluded as there was no full text available and the information could not be gleaned from the abstract. Three were the ‘wrong setting’, which included a letter to the author, a study that was for termination of pregnancy and one that explored women’s concerns about contraception, rather than their experience. One was excluded for ‘wrong population’ as it was a study asking never users about contraception and this is the wrong group of patients.

One hundred and eleven studies were suitable for final data extraction stage. All one hundred and eleven studies were reviewed by the first author and all that were excluded (60 papers) were reviewed by the second researcher, as well as 10% of the studies included (11 papers). There were two conflicts, which were resolved and remained in the included group.

#### 2.1.4.4 Final Data Extraction

The final one hundred and eleven papers were analysed by the first author and information on the title, author and which questionnaire(s) was used was tabulated (Appendix ..).

### 2.2 Questionnaire Analysis

The most commonly used questionnaires that appeared in the search were analysed for their suitability. Two of the contraception specific questionnaires that were found were analysed in more detail, using the COSMIN checklist, to assess the quality of the instruments. However, as the COSMIN checklist is currently undergoing some changes, to include information on the conceptual underpinnings of the measure being assessed, the questionnaires were also assessed against the Ferrans and colleagues' model (described above), for completeness.

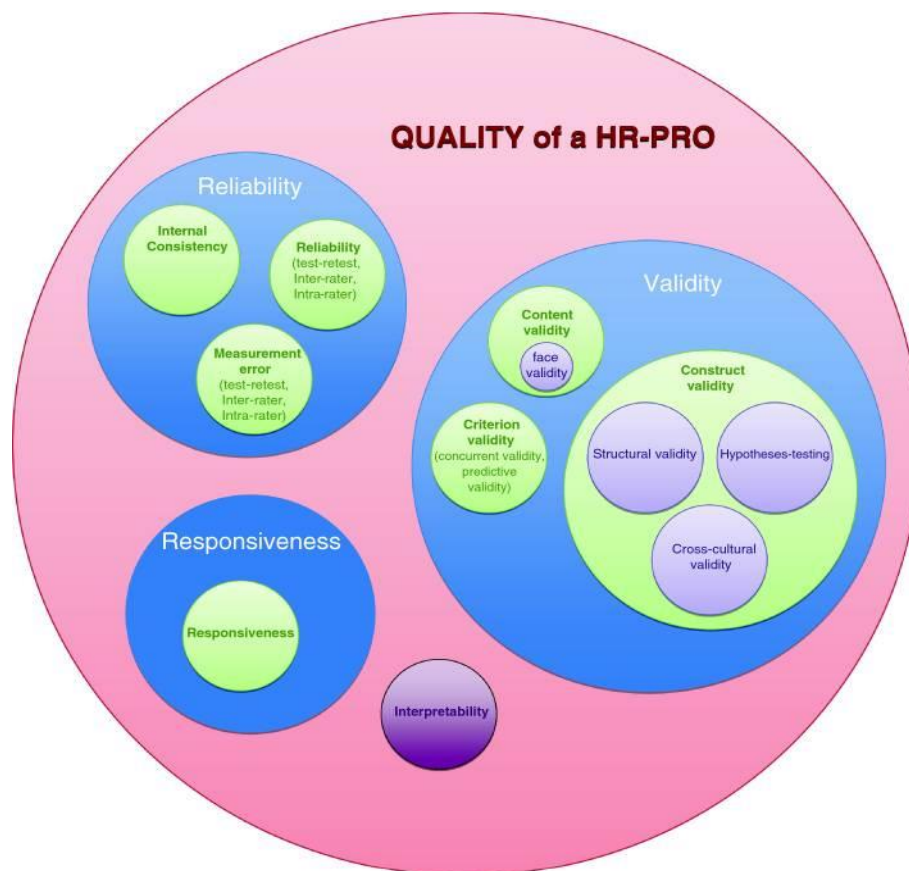
#### 2.2.1 How to Analyse a QoL Instrument

It is important to have a rigorous method in which to analyse and compare health questionnaires. Therefore, there must be criteria to follow when creating an instrument or indeed critiquing one. Several authors have offered benchmarks for evaluating QoL instruments or measures. The most well-known and perhaps the forerunner in the field is the criteria from the Scientific Advisory Committee (SAC) of the Medical Outcomes Trust. In order to promote the science and application of HRQOL measures, they set out eight key attributes to HRQOL measures;<sup>52</sup> 1. *Conceptual and measurement model* – a conceptual model describes the concepts and the population under assessment and the relationship between them. A measurement model is to do with the scales used in the instrument and their suitability.<sup>52</sup> In order to select the questions for the questionnaire, the classical test theory (CTT) approach may be employed or an item response theory (IRT) approach may be used. The CTT approach was coined by Lord and Novick in 1968.<sup>53</sup> It is a theory based on workings that the score obtained through the questionnaire is the sum of the true score and the error score, which gives us the observed score of the person answering the questionnaire, with the true score being a perfect score, without error. In other words, the purpose of the CTT is to predict the outcome and measure the reliability of a psychometric test through the score of the individual taking the test and the amount of errors within the test itself.<sup>54</sup> A more modern model is the IRT, which describes the association between the respondent's ability with the probability of the item response. IRT models are unidimensional in that they only measure one construct per scale and each item is locally independent of each other, thus assuming that all questions are varying levels of difficulty.<sup>55</sup> 2. *Reliability*; this measures how free of random error the instrument is. Test reliability is measured using Cronbach's coefficient,  $\alpha$  and by assessing reproducibility (e.g test-retest reliability).<sup>52</sup> Both CTT and IRT use Cronbach's coefficient to look at internal consistency and test-retest reliability to determine the reliability of the instrument.<sup>56</sup> 3. *Validity*; does the instrument measure what it has set out to? Evidence can be classified in three ways – content-related, construct-related and criterion-related. 4. *Responsiveness*; can the instrument detect change? This is sometimes referred to as sensitivity to change. 5. *Interpretability*; this is the ability to translate quantitative data into qualitative meaning. 6. *Respondent and administrative burden*; what is the time, effort and other demands of both the person completing the questionnaire and the administrator of the questionnaire? 7. *Alternate forms*; the developer should evaluate all forms of the

questionnaire, for example, interview, phone, by proxy, self-administered in all the aforementioned criterion. 8. *Cultural and language adaptations*; has the questionnaire been translated into a different language or adapted for use within a different culture? If so, how was this done and what are the differences?<sup>52</sup>

### 2.2.2 The COSMIN Checklist

The COSMIN checklist (CONsensus-based Standards for the selection of health status Measurement INSTRUMENTs) is similar to the SAC criteria but it is more current way of evaluating HRQOL instruments. It can be used to assess the methodological quality of a study of the measurement properties of a questionnaire.<sup>57</sup> It will be used in this paper to assess the ORTHO BC-SAT and the SEC-QOL. It contains twelve boxes, ten of which are used to determine whether the study meets the standards for good methodological quality. Nine of these boxes contain standards that are similar to those standards set out by the SAC, described above. These nine boxes in the COSMIN checklist are *internal consistency*, *reliability*, *measurement error*, *content validity*, *structural validity*, *hypothesis testing*, *cross-cultural validity* and *responsiveness*. The tenth box (interpretability) is used to record the percentage of missing items and to calculate the distribution of scores. There are a further two boxes which are used specifically for articles in which IRT is applied<sup>58</sup>. The checklist uses a 4-point scale to give a score of excellent, good, fair or



**Fig 5.** COSMIN taxonomy of relationship of the 10 measurements of the checklist.  
Figure taken from Mokkink et al., 2010.

poor for each of the domains. The COSMIN checklist should be used to evaluate studies that validate a paper and is not used to directly assess the quality of HRQOL measure itself<sup>58</sup>. FDA guidelines state that analysis should include a question on the conceptual model of the measure being assessed, which the COSMIN checklist currently does not. However, this is under review and it is likely to in the future.<sup>3</sup>

### *2.3 Preliminary Pretesting*

Preliminary pretesting is generally used to evaluate a questionnaire in advance of testing it on interviewers and respondents.<sup>59</sup> For this study, a sample of women of reproductive age were asked to fill in the ORTHO BC-SAT questionnaire and give feedback on its suitability.

The ORTHO BC-SAT was chosen over the SEC-QOL as it is longer, covers more domains, enquires about a wider range of side effects and also covers overall satisfaction. It was also advantageous as the original ORTHO BC-SAT questionnaire was obtained with permission for use from the author (Appendix). The ORTHO BC-SAT is also written in English, whereas the SEC-QOL was only available as a translation of the Spanish version and needs rewording before testing.

The respondents were made up of a group of 20 women aged between 19 and 29. They were all university educated, from a variety of different backgrounds, working in a variety of different jobs. The respondents were asked to fill in the questionnaire, stating what contraception they were on. The respondents were asked to answer the following:

1. Comment on the overall suitability of the questionnaire.
2. Were all relevant points covered?
3. Is there anything you would add or take away from the questionnaire?
4. Do you feel that all effects, including the sexual effects of contraception were covered appropriately?

### 3.0 Results

This section will firstly summarise the results of the literature search by displaying all the HRQOL measures that were identified through the literature search. Secondly, the two of the contraception specific questionnaires (ORTHO BC-SAT and SEC-QOL) will be analysed using the COSMIN checklist and Ferrans model. Thirdly, the preliminary pretesting data will be presented.

#### 3.1 Health-Related Quality of Life Measures

From a total of 111 papers, fifty-nine validated tools were identified (Table 1). Many studies used more than one questionnaire and so the total number of questionnaires used, throughout the 111 studies, was 170. General HRQOL measures were used most commonly, with a combined total of 78 times (45.8%)(Table 1).

General	Freq.
Short-Form-36 Questionnaire	30
EQ-5D	8
Quality of Life and Satisfaction Questionnaire (Q-LESQ)	6
Rand-36	5
Short Personal Experience Questionnaire (SPEQ)	3
Visual Analogue Scale (VAS)	3
WHOQoL	3
EQ-5D VAS	2
SF-12	2
SF-36v2	2
Women's Health Questionnaire	2
Daily Record of Severity of Problems (DRSP)	1
EORTC QLQ-C30	1
EQ-5D-3L	1
General Effect Study Medication Questionnaire (GESQ)	1
General Health Questionnaire GHQ-12	1
HRQL (SF-8)	1
HRQOL 24	1
Short-Form Questionnaire-6 Dimensions (SF-6D)	1
Sickness Impact Profile	1
WHO-S	1
WHOQoL-BREF	1
Youth Quality of Life Instrument	1
	78

**Table 1.** Names and corresponding frequencies of general HRQOL tools found in the literature search.

Of the 59 tools identified, four were contraception specific, namely the ORTHO BC-SAT, the SEC-QOL, The EVAPIL Scale<sup>60</sup> and The NuvaRing Acceptability Questionnaire.<sup>61</sup> The frequency of use was 3 (1.76%) for both the ORTHO BC-SAT and the SEC-QOL and 1 for both the EVAPIL (0.58%) and The NuvaRing Acceptability Questionnaire. Within the 170 studies, contraception specific HRQOL measures were used a total of 8 times (4.7%)(Table 2).

Contraception Specific	freq.
ORTHO BC-SAT	3
SEC-QOL	3
EVAPIL	1
NuvaRing Acceptability Questionnaire	1
	8

**Table 2.** Names and corresponding frequencies of contraception specific HRQOL tools found in the literature search.

17 of the 59 tools used were HRQOL questionnaires that were designed to measure sexual function. Within the 111 studies identified in this search, sexual wellbeing HRQOL measures were used a combined total of 17 times (10%) (Table 3).

Sexual Wellbeing	Freq.
Female Sexual Function Index (FSFI)	8
Female Sexual Distress Scale	2
Mell-Krat Scale (FSK-K)	2
Sexual Activity Questionnaire	2
Derogatis Sexual Functioning Inventory (DSFI)	1
Golombok Rust Inventory of Sexual Satisfaction (GRIS)	1
McCoy Female Sexuality Questionnaire	1
	17

**Table 3.** Names and corresponding frequencies of sexual wellbeing HRQOL tools found in the literature search.

There are many validated HRQOL questionnaires which are designed to assess psychological wellbeing such as the Beck's Depression Inventory and the Psychological Global Well-Being Inventory. In this study, 17 of the HRQOL measures identified were created for the purpose of assessing psychological wellbeing and were used a total of 38 times (22.3%) throughout the 111 studies (Table 4).

Psychological Wellbeing	Freq.
Becks Depression Inventory (BDI)	9
Psychological Global Well-Being Inventory (PGWBI)	7
Profile of Moods States (POMS)	4
Hamilton Depression Rating Scale	2
Hospital Anxiety and Depression Scale	2
Penn State Daily Symptom Report (DSR17)	2
Scott and White (S&W) Mood Scale	2
Amsterdam Mood Questionnaire	1
Centre for Epidemiological Depression Scale	1
Eight State Questionnaire	1
Hamilton Anxiety Scale	1
Montgomery-Åsberg Depression Rating Scale (MADRS)	1
Multiple Affect Adjective Checklist Revised	1
Positive and Negative Affect Schedule (PANAS)	1
Symptom Checklist-90 (SCL-90)	1
Taylor Manifest Anxiety Scale	1
Undergraduate Stress Questionnaire (USQ)	1
	38

**Table 4.** Names and corresponding frequencies of psychological wellbeing HRQOL tools found in the literature search.

Seven of the HRQOL tools were identified as being for the purpose of assessing a specific condition or illness. For example, the Moos MDQ is used to assess menstrual symptoms and the PCOSQ (polycystic ovary syndrome questionnaire), which was designed to assess the QoL of women with PCOS. This type of HRQOL was used a combined total of 26 times (15.3%)(Table 5).

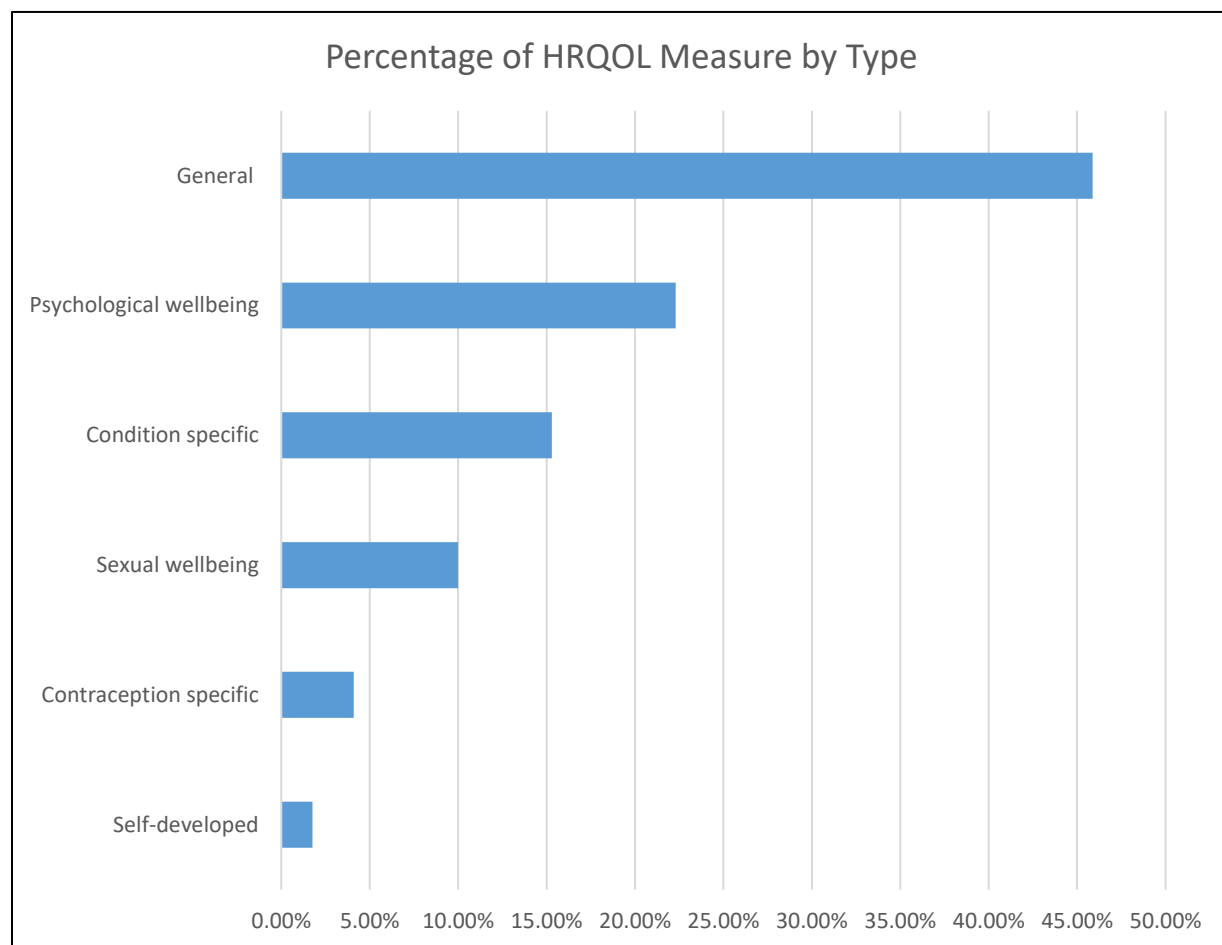
Specific	Freq.
Moos Menstrual Distress Questionnaire (MDQ)	18
Eysenck Personality Index	2
Menorrhagia Multi-Attribute Scale (MMAS)	2
Bem Sex-Role Inventory	1
Menstrual Health Questionnaire	1
PCOSQ	1
Traumatic Antecedents Questionnaire (TAQ)	1
	26

**Table 5.** Names and corresponding frequencies of condition specific HRQOL tools found in the literature search.



Two studies (1.2%) developed their own questionnaire for use.<sup>62,63</sup> The first study was a German study and no full text is freely available. The abstract states that QoL changes were evaluated through a 20-item, 5-point scale, self-developed questionnaire but no further information is available.<sup>63</sup> The second of the studies was designed to evaluate the use of the LNG-IUS in women with haemostatic disorders and abnormal uterine bleeding. This was a 10-item QoL questionnaire which assessed the following parameters: general activity, ability to go to work/school, sleeping, mood, participation in family activities, enjoyment of life, pain during menstruation, ability to enjoy sexual intercourse, overall QoL and general health.<sup>62</sup> This seems to cover all the important points but it is lacking in depth and was made specifically for women with haemostatic disorders. However, as a short assessment of HRQOL with regards to contraception, and on face value, this is a good measure. However, it has not undergone validity and reliability testing.

The breakdown of use of the different types of HRQOL measures used can be visualised in the graph below (Fig. 6)



**Fig. 6.** Corresponding percentage of HRQOL by type.

HRQOL Measure	n=	HRQOL Measure	n=
Short-Form-36 Questionnaire	30	Centre for Epidemiological Depression Scale <sup>2</sup>	1
Moos Menstrual Distress Questionnaire (MDQ)	18	Daily Record of Severity of Problems (DRSP) <sup>2</sup>	1
Beck Depression Inventory (BDI)	9	Derogatis Sexual Functioning Inventory (DSFI)	1
EQ-5D	8	Eight State Questionnaire	1
Female Sexual Function Index (FSFI)	8	EORTC QLQ-C30	1
Psychological Global Well-Being Inventory <sup>2</sup> (PGWBI)	7	EQ-5D-3L	1
Quality of Life and Satisfaction Questionnaire <sup>2</sup> (Q-LESQ)	6	EVAPIL	1
Rand-36	5	General Effect Study Medication Questionnaire <sup>2</sup> (GESQ)	1
Profile of Moods States (POMS)	4	General Health Questionnaire <sup>2</sup> 12	1
Self-developed	4	Golombok Rust Inventory of Sexual Satisfaction (GRIS)	1
ORTHOBCSAT	3	Hamilton Anxiety Scale	1
SEC-QOL	3	HRQL (SF-8)	1
Short Personal <sup>2</sup> Experience Questionnaire (SPEQ)	3	HRQL <sup>2</sup> 4	1
Visual Analogue Scale (VAS)	3	MADRS-S.	1
WHOQoL <sup>2</sup>	3	McCoy Female Sexuality Questionnaire	1
EQ-5D <sup>2</sup> vas	2	Menstrual Health Questionnaire	1
Eysenck Personality Index	2	Multiple Affect Adjective Checklist Revised	1
Female Sexual Distress Scale	2	PCOSQ	1
Hamilton Depression Rating Scale	2	Positive and Negative Affect Schedule (PANAS)	1
Hospital Anxiety and Depression Scale <sup>2</sup>	2	SCL-90	1
Mell-Krat Scale (SFK-K)	2	Short Form Questionnaire-6 Dimensions (SF-6D)	1
Menorrhagia Multi-Attribute Scale (MMAS)	2	Sickness Impact Profile	1
Penn State Daily Symptom Report (DSR17)	2	TAQ	1
Scott and White (S&W) Mood Scale <sup>2</sup>	2	Taylor Manifest Anxiety Scale	1
Sexual Activity Questionnaire	2	USQ	1
SF-12 <sup>2</sup>	2	Unknown	1
SF-36v2	2	VRS	1
Women's Health Questionnaire	2	WHO-S	1
Amsterdam Mood Questionnaire	1	WHOQoL-BREF	1
Bem Sex-Role Inventory	1	Youth Quality of Life Instrument	1

**Table 6.** Complete list of validated questionnaires used within the 111 studies and corresponding frequencies. n= number of times used within the 111 studies.

### 3.2 Analysis of Contraception Specific Health-Related Quality of Life Instruments

#### 3.2.1 ORTHO BC-SAT Analysis

The ORTHO Birth Control Satisfaction Assessment Tool (ORTHO BC-SAT) is a 42 item, self-administered questionnaire that assesses eight domains: future fertility concerns, convenience of use, compliance, lifestyle impact, side effect profile, impact on menstruation, assurance/confidence and overall satisfaction<sup>64</sup> (Appendix). Women are asked to respond on a Likert scale of between five and seven options (Fig. 3).

#### 6. How bothered were you by the following symptoms during the past month?

	Did not have	Not at all bothered	A little bothered	Somewhat bothered	Very bothered	Extremely bothered
a. Breast tenderness	<input type="checkbox"/>	1	2	3	4	5
b. Feeling moody	<input type="checkbox"/>	1	2	3	4	5
c. Feeling irritated	<input type="checkbox"/>	1	2	3	4	5
d. Acne (pimples)	<input type="checkbox"/>	1	2	3	4	5
e. Cramping/pelvic pain	<input type="checkbox"/>	1	2	3	4	5
f. Spotting/bleeding between periods	<input type="checkbox"/>	1	2	3	4	5
g. Headaches	<input type="checkbox"/>	1	2	3	4	5
h. Bloating	<input type="checkbox"/>	1	2	3	4	5
i. Nausea	<input type="checkbox"/>	1	2	3	4	5
j. Weight gain	<input type="checkbox"/>	1	2	3	4	5
k. Hair loss/ hair thinning	<input type="checkbox"/>	1	2	3	4	5

**Fig. 7** Example question from ORTHO BC-SAT about menstrual symptoms

The questionnaire was developed by Mathias et al.,<sup>65</sup> and funded by Ortho-McNeil Pharmaceutical, Inc., producer of the ORTHO EVRA transdermal contraceptive patch. The questionnaire was designed by holding one-to-one telephone interviews with doctors, holding focus groups and pretesting sessions with women of reproductive age on one of four hormonal contraceptives. The psychometric properties of the questionnaire were then tested in a validation study, which deemed the questionnaire to be reliable and valid.<sup>64,66</sup>

This is the first questionnaire that has been developed to specifically assess the satisfaction of women with their contraceptive methods. However, it must be noted that this questionnaire assesses 'satisfaction' rather than QoL and is also limited to hormonal contraception.

It is difficult to assess the ORTHO BC-SAT against the Ferrans model for HRQOL measures as it is not technically a HRQOL tool – it is a satisfaction assessment tool. It is a specific tool that covers important domains such as fertility concerns, menstrual symptoms, convenience of use and compliance, all of which are specific to contraception and thus don't directly fit into the domains

of Ferrans model. However, there are similarities; 'Biological functions' are captured by the menstrual symptoms questions and 'symptoms' are covered by various questions about menstrual symptoms and effect on mental health. 'Functional status' is assessed by questions about limits on sex, life, work and daily activities. 'General health perceptions' is the assessment of all the above. As it is a satisfaction assessment tool, the final question asks how satisfied overall the woman is with her contraception, rather than how happy she is with her overall QoL. The author states that the domains covered are future fertility concerns, convenience of use, compliance, lifestyle impact, side effect profile, impact on menstruation, assurance/confidence and overall satisfaction as opposed to the five suggested by Ferrans and colleagues.

#### *3.2.1.1 Strengths and Limitations of ORTHO BC-SAT*

There are several limitations and criticisms of this questionnaire. Firstly, it is important to note that this questionnaire assesses satisfaction, not HRQOL of women on contraception. It is not clear from the author why they chose to make it a satisfaction assessment tool rather than a HRQOL tool. As previously mentioned, using a standard model for HRQOL allows us to compare across research in a particular field. By using a satisfaction tool, it makes comparison more difficult and this is a shortcoming of the tool. Besides, satisfaction is a factor of QoL and so the questionnaire could have easily been developed into a HRQOL tool. When assessing the validity of the tool, the author marks it next to the SF-12v2 and the Mental Health Index-5 (MHI-5) questionnaires, which are both HRQOL tools and as such, it would have been a better comparison if the ORTHO BC-SAT was also a HRQOL tool.

Secondly, its production was funded by Ortho-McNeil Pharmaceutical, Inc. - manufacturer of the ORTHO EVRA transdermal contraceptive patch. Studies funded by large pharmaceutical companies with a product in the field should always be approached with caution. In this case, it is not clear what, if any, gain there was for Ortho-McNeil Pharmaceutical, Inc. It may be relevant that the healthcare system is different, as well as privatised, in America and there is perhaps more financial gain to be had by pharmaceutical companies in a private healthcare system. It was not mentioned if there was any financial incentive for women to take part in their research and this could have influenced the group demographics. The age, relationship status, ethnicity and education level was given of the 339 women who were part of the validity study. The majority (88%) were Caucasian. Minority ethnic groups are less likely to use the pill and more likely to feel let down by reproductive services in America<sup>67</sup> so a more diverse group would have been beneficial. The questionnaire itself does not ask for demographic details, which it should, or they should at least be determined alongside as, as Ferrans et al., explain, the environmental and individual influences is vital data and allow comparison between studies.<sup>5</sup> Additionally, as the questionnaire was developed in America, is it understandably Americansied in its terminology and uses 'birth control' instead of 'contraception'. For a British cohort, it would be far more relatable to use the term 'contraception'.

Furthermore, the questionnaire was only tested on 4 types of hormonal contraception – the ring, patch, pill and injection. There was also no differentiation made between the COCP and the POP and as previously discussed they can have a very different side effect profile and are used for different groups of women. Further studies should be done to include the other types of

contraception. The questionnaire is only useful for wide use if it can be used for all women on all types of contraception. Also, the questionnaire addresses concerns about pregnancy and fertility but fails to address concerns about sexually transmitted infections (STI's), which of course is an important consideration when using a non-barrier method of contraception.

As mentioned many times throughout this paper, sexual quality of life (SQoL) forms a fundamental part of HRQOL and should be assessed in this specific circumstance. The only questions asked in the ORTHO BC-SAT are "The side effects of my birth control interfere with my sex life" and "My sex life has become more spontaneous with my current birth control". Compared to the 19 questions asked in the FSFI, this is an inadequate assessment of sexual function and satisfaction. It is important that the questionnaire is not too long so it would not be suitable to include all 19 questions, but more than 2 questions would be appropriate, in place of others, particularly those that are repetitive.

### *3.2.2 SEC-QOL Analysis*

The SEC-QOL (Sociedad Española de Contracepción (Spanish contraception Society) Quality of Life) questionnaire is a HRQOL questionnaire, developed in Spain. There is an English translation available but the author states that the cultural adaptation procedure was not followed. It was developed following interviews with 14 women who were using hormonal or non-hormonal contraception. A draft questionnaire was then tested on 187 women. Rasch analysis was applied in order to reduce 41 questions down to 19.<sup>68</sup>

The final version consists of 19 different questions, covering five different domains: social (5 items), menstrual symptoms (4 items), breast symptoms (3 items), psychological (4 items), and sexual (3 items) (see appendix for full questionnaire) and asks the women to rate their answer on a 5-point Likert scale from always to never or totally agree to totally disagree. For example, question number one states "I have menstrual pain (pain in the lumbar area and abdomen) a few days before my period starts" and the woman has to rate this from 'almost always' to 'almost never'.

When assessed against Ferrans and colleagues model for HRQOL, it is again difficult to draw comparisons. Three of the five domains within the SEC-QOL are specific to contraception (menstrual symptoms, breast symptoms and sexual) and therefore does not match up with the five general domains of Ferrans' model. It could be argued that, as with the ORTHO BC-SAT, the first four domains (biological functions, symptoms, functional status and general health perceptions) are covered by the questions asked, but they are named in a different way. The fifth domain (overall QoL) is not covered as no question is asked about overall QoL in the SEC-QOL.

#### *3.2.2.1 Strengths and Limitations of SEC-QOL*

A strength of the SEC-QOL questionnaire would be that it explores all the relevant menstrual symptoms. Concerns about failure of contraception, symptoms of nervousness and sexual desire are also covered in this questionnaire, albeit briefly.

One of the main limitations of the questionnaire is that it has not been culturally adapted, it has just been simply translated into English. This would need cultural adaptation through the appropriate means as recommended by the SAC<sup>52</sup> before it could be used in the UK.

Its brevity is both a strength and a limitation. On one hand, a short questionnaire is user-friendly and easy to economically evaluate. On the other hand, it could be argued that the SEC-QOL does not go into as much depth as is needed. It only really covers symptoms and the associated limitations on activity and does not establish anything about ease of use or compliance, as the ORTHO BC-SAT does. It also does not ask a question about overall QoL. In this way, it is more similar to the Moos MDQ than it is to the ORTHO BC-SAT. The ORTHO BC-SAT covers far more symptoms and asks questions about fertility concerns, which the SEC-QOL fails to do.

The two questions about sexual desire are “My sexual desire decreases during the days of my period.” and “During the first few days of my period, when bleeding is heavier, I refuse sexual intercourse.” These questions do not cover the full breadth of side effects that contraception can have.

A study which uses the SEC-QOL questionnaire to assess the QoL of women using the LNG-IUS, argues that the use of a specific contraception QoL tool, that assesses the five domains is a unique and valuable way of assessing the QoL of women over time. Their study shows an improvement in HRQOL over 12 months in the women using the LNG-IUS.<sup>69</sup>

### *3.2.3 The NuvaRing acceptability Questionnaire*

One study developed an acceptability questionnaire as part of a research programme to determine the efficacy and safety of the NuvaRing vaginal contraceptive ring – ‘The NuvaRing acceptability Questionnaire’.<sup>61</sup> This is 21 question questionnaire covering: ring use, clarity of instructions, sexual comfort, cycle-related characteristics, compliance and satisfaction (appendix). It is very specific to vaginal ring use and is not transferrable to any other form of contraception. There is also space for free writing and this makes it difficult to statistically analyse. For this reason, and within the limitations of this study, this questionnaire will not be analysed in any further detail.

### *3.2.4 The EVAPIL Scale*

The EVAPIL Scale was designed to measure the.....

### 3.2.5 COSMIN checklist for ORTHO BC-SAT and SEC-QOL

The ORTHO BC-SAT and the SEC-QOL were assessed using the COSMIN checklist, as outlined previously. The results are tabulated below:

<b>Paper</b>	<i>"The ORTHO BC-SAT – a satisfaction questionnaire for women using hormonal contraceptives"</i> <sup>64</sup>	<i>"Development and Validation of the SEC-QOL Questionnaire in Women Using Contraceptive Methods"</i> <sup>68</sup>
<b>Instrument</b>	<b>ORTHO BC-SAT</b>	<b>SEC-QOL</b>
<b>CTT or IRT</b>	CTT	IRT
<b>Internal consistency</b>	Fair	
<b>Reliability</b>	Good	
<b>Measurement Error</b>	Good	
<b>Content validity</b>	Excellent	
<b>Structural validity</b>	Poor	
<b>Hypothesis testing</b>	Fair	
<b>Cross-cultural validity</b>	n/a	
<b>Criterion validity</b>	Good	
<b>Responsiveness</b>	n/a	

**Table 7** The COSMIN checklist review of the ORTHO BC-SAT and the SEC-QOL.

### 3.3 Preliminary Pretesting Data on the ORTHO BC-SAT

The ORTHO BC-SAT was sent out to 40 women. Twenty women returned the questionnaire (50%). The women in general were very keen to discuss their contraception and several commented that they enjoyed having the chance to think about the effects of their contraception and offload that in some way. When asked to comment on the suitability of the questionnaire, the women responded with; "I liked it", "I think it's great", "It's easy to follow and good", "Overall, I thought it was beneficial"

Suggestions for adding or taking away any questions included adding questions to ascertain what contraception the female had tried before and why they stopped/changed it and how easy it was to change, asking about how many different types of contraception had been tried before and if they would consider changing their method after reflecting on this questionnaire. Another suggestion from a woman who was using the Mirena coil to help with endometriosis thought it would be a good idea to ask if there was a medical reason as to why they are on the method that they are. One woman made specific reference to the mental health aspect of the questionnaire and thought that the questions did not cover enough depth about the negative effects of contraception on mental health. She felt that the questions "how bothered are you by... feeling moody/feeling irritated?" were not enough for her to convey how badly her mental health has been effected by her contraception choice. Two other women also suggested better coverage on the effects non mental health. Women using the IUS suggested a question to ask about pain on

insertion and recovery following that as they felt that the pain associated with insertion would prevent them from recommending it to a friend.

Several comments were also made about the length of the questionnaire as well as ease of completion. Many thought it was too long and annoying to complete in Word form. For the purposes of this study, I sent out a word document to be filled in electronically and sent back. Various women suggested that an online survey would have been easier to complete and more suitable for the target audience. This should be kept in mind for future developments. A couple of women thought that there was repetition and that alternative questions could have been asked in their place. For example, one woman suggested that questions 1-3 and 9b, 9c and 9q could all be covered in one question (relating to convenience of use) and that overall the questionnaire could be more succinct. One woman noted that the questions 9e – “The side effects of my birth control interfere with my everyday life” and 9h – “My birth control interferes with my daily activities” are very similar and stated that she didn’t understand why both were asked. Two women thought the question “My birth control is only known to those I choose to tell or show (i.e., I am able to keep my birth control private).” was a peculiar question to ask and perhaps unnecessary.

When asked about the sexual aspects of the questionnaire, women thought that it did not cover very much at all. One women said “I didn’t feel like it asked about my sex life at all”. Another woman remarked that the question, “My sex life has become more spontaneous with my current birth control.” would only be relatable if she was not in a relationship and was only sleeping with men on a one night only basis. Other comments included “I would have liked a question about how my mental health has affected my libido” and “I don’t feel like having sex at all since starting my new pill – the questionnaire didn’t ask me anything about sexual frequency or desire”.

A common remark was also that women wanted a white space to elaborate on their answers. Whilst this would be difficult to quantify statistically, it maybe suggests that women did not feel like they are being asked enough or that they feel something was missed in the questionnaire.



## 4.0 Discussion

This section will discuss the most commonly used generic HRQOL measures and conclude whether they are fit for this purpose. It will then outline the strengths and limitations of the study. The conclusion of the study will then be presented.

### *3.1.1 The Short Form 36*

The Medical Outcomes Study (MOS) Short Form 36 (SF-36) was the most commonly used questionnaire and was used a total of 30 times, throughout the 111 studies identified. The SF-36 was constructed in 1992 by RAND<sup>6</sup> and contains thirty-six items which assess eight health concepts; limitations in physical activity, social activity, usual role, pain, mental health, limitations due to mental health, energy and fatigue and general health perceptions. It can be used in various health settings and was designed to be used by any person over the age of 14. There have since been variations of the questionnaire, to include the SF-36v2, the SF-12v2 and the SF-8 which all measure the same health domains.

The SF-36 contains questions such as “During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?” and “The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?” in relation to; “1. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports, 2. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf, 3. Lifting or carrying groceries, 4. Climbing several flights of stairs....” (full questionnaire in Appendix). It is clear to see that whilst these activities may be affected by cramping, abdominal pain and emotional distress, this questionnaire does not assess the specific limitations that may be brought about by contraception, such as security in a relationship, fears of pregnancy, sexual activity and relationship satisfaction. Neither does it cover specific symptoms such as headache, breast tenderness, fear of side effects and compliance to contraception. All these things are very specific to contraception use and a questionnaire that is as general as the SF-36 is not suitable for assessing such specific circumstances. Furthermore, a young woman who is being assessed in relation to her contraception may find it strange to be asked about her limitations on bowling and playing golf.

If we take, for example, one of the studies from the literature search that used the SF-36 – ‘*Levonorgestrel Intrauterine System versus Medical Therapy for Menorrhagia*’ by Gupta et al.,<sup>70</sup> This study wanted to assess the effect of the intrauterine system on menorrhagia and used the Menorrhagia Multi-Attribute Scale (MMAS) as their primary outcome measure. The MMAS is a questionnaire that covers six domains related to the restrictions brought about by heavy menstrual bleeding (HMB). It assesses the practical, social, psychological, physical limitations as well as the effect on work and family life.<sup>71</sup> They then used the SF-36 as their secondary outcome measure as well as the EQ-5D and the EQ-5D visual analogue scale to assess the impact on general QoL. So, whilst the women would have been able to comment on whether their improvement in menorrhagia increased their ability to climb stairs, lift groceries and walk several blocks, it would

have been far more beneficial for this study to use a specific questionnaire to QoL related to contraception use. Although the primary objective was to relieve the patient of HMB, the LNG-IUS could have had many other specific positive and negative effects and a contraception specific questionnaire would have captured this much better.

### 3.1.2 Moos Menstrual Distress Questionnaire

The Moos Menstrual Distress Questionnaire (MDQ) was developed in 1968.<sup>72</sup> It is a 46-item self-report questionnaire designed to assess premenstrual and menstrual symptoms. Form C explores symptoms before, during and after menstruation and Form T studies symptoms on the day of taking the questionnaire. It asks the participator to rate each menstrual symptom on a scale from one to six, covering the areas of pain (including muscle stiffness, headache, cramps, backache), concentration (including insomnia, forgetfulness, confusion and distractibility), behavioural change (such as lowered school/work performance, naps and avoidance of activity), autonomic reactions (dizziness, cold sweats, nausea, vomiting, hot flushes), water retention (including weight gain, skin changes, painful breasts and swelling), negative affect (such as crying, loneliness, anxiety and mood swings), arousal (including affection and bursts of energy) and control (to include symptoms such as chest pain, pounding heart, numbness and blind spots).<sup>72</sup> It's surprising that the MDQ is the second most commonly used questionnaire in this search as it has been so heavily criticised since its creation.<sup>73</sup> It has been shown that there was a lack of research into the reliability and validity of the MDQ and there is also criticism that the MDQ measures concepts unrelated to the menstrual cycle.<sup>74</sup> Now, if we take, for example, the study *"Effects of oral contraceptives containing ethinylestradiol with either drospirenone or levonorgestrel on various parameters associated with well-being in healthy women: a randomized, single-blind, parallel-group, multicentre study."* by Kelly et al.,<sup>75</sup> to consider the use of the MDQ. They wish to compare two contraceptive pills – Yasmin and Microgynon, as they state that Yasmin has been shown to have a positive effect on QoL, as well as menstrual symptoms. They then go on to use the MDQ to measure this. So, not only are they using a questionnaire that has been heavily criticised for its construction, they are also using a questionnaire that does not assess QoL, even though that's what they set out to show an improvement in. They would have gained so much more from using a questionnaire that was validated and specific for the use of assessing QoL in relation to contraception.

The Moos MDQ, although criticised, covers all the relevant menstrual symptoms and Form T of the questionnaire can be used to track improvement in menstrual symptoms when on contraception. However, it does not assess overall QOL and is therefore just a symptoms checker. Furthermore, aside from 'affection' as a 'symptom' of menstruation, it does not assess sexual concerns such as libido and lubrication which, as already discussed, is an essential part of HRQOL.

### 3.1.3 EQ-5D

The EQ-5D was the fourth most commonly used questionnaire in this search but is pertinent to this study as it was considered for use in the Contraception Choices Project. The EQ-5D is one of a few versions of the questionnaire, produced by the EuroQol group in 1990<sup>76</sup>. There are 5 dimensions (5D) and depending on the version, either a 3-point scale (EQ-5S-3L) or a 5-point scale

(EQ-5D-5L) is used. There is also a version designed for younger patients (EQ-5D-Y) and the EQ-VAS (visual analogue scale).<sup>77</sup> The 5 dimensions are mobility, self-care, usual activities, pain and anxiety/depression.<sup>78</sup> One question is asked on each of these dimensions, with a scale to answer. For example, for 'mobility', for the EQ-5D-3L; 'I have no problems in walking about, I have some problems in walking about and I am confined to bed'. It was designed to act as a compliment to other HRQOL and to be generalised for use across many specialties, instead of being disease specific.<sup>78</sup> This gives an extremely brief overview of the 5 domains, but has very little correlation to the effects of contraception so would not be suitable for the purposes outlined in this study either.

#### *4.1 Strengths of Study*

To our knowledge, there has been no previous review of this nature, demonstrated by the fact that no such study was found in the search itself. This study has highlighted an important gap in research and has emphasised the need for a HRQOL tool that can be used to assess women of reproductive age, who are using contraception.

This study not only assessed the contraception specific HRQOL measures but it also evaluated the most commonly used HRQOL measures and gave reasons as to why they are not suitable for the purpose of assessing HRQOL in relation to contraception.

Furthermore, women of reproductive age were asked about their views on one of the contraception specific contraecpetion measures and this preliminary pre-testing highlighted several flaws in the ORTHO BC-SAT and gives a good basis for further research.

#### *4.2 Limitations of Study*

Though thorough, this search was not complete. It was limited to 4 databases and did not search unpublished data, grey literature or more databases.

The preliminary pre-testing data obtained was also limited. A small cohort of educated women was asked about their views on the ORTHO BC-SAT. Further research should focus on asking a larger population of women, from a wider range of socio-economic and educational backgrounds. Ideally, the women should have also been asked to complete the SEC-QOL and give feedback on that as well and benefit would have been gained from asking them to compare the two and then compare to a general HRQOL measure such as the SF-36. There is certainly scope for more qualitative research in this area.

#### *4.3 Recommendations for Future Work*

The next steps to this work should include additional qualitative research with focus groups of women from a variety of different backgrounds and of various ages to determine the most relevant questions. The ORTHO BC-SAT should be evaluated by more women and the SEC-QOL should be given to women to assess also. It would also be beneficial to gain women's opinions on using generic measures such as the SF-36 and the EQ-5D for this purpose. The ORTHO BC-SAT

was designed for an American cohort and the SEC-QOL was for use in Spain. Therefore, they should be assessed on a British cohort.

Bakas et al.,<sup>2</sup> suggest that HRQOL research should use common global HRQOL models in order to be able to compare cross-study. If they don't, they suggest that authors should make it clear why not. In the context of contraception, I think there is an argument that general HRQOL questionnaires do not capture the effects of contraception on women's lives and many of the questions are irrelevant, as previously discussed. Therefore, I believe that there is scope for a contraception specific HRQOL measure and the following points should be considered:

1. The questionnaire should include several questions on sexual function/dysfunction, libido, sexual satisfaction, dyspareunia and vaginal dryness.
2. The questionnaire should contain questions about the effect of contraception on mental health and focus groups should be held to determine which questions to ask.
3. The Ferrans and Colleagues model for HRQOL research should be followed to make a robust and comparable HRQOL measure that contains all the right domains.
4. The COSMIN checklist should be applied afterwards to assess the overall methodological quality of the questionnaire.

HRQOL instruments are useful when they are used to assess what they have been designed to assess. A questionnaire that works well in one setting, may be completely useless in another setting or with a different population. Studies should be clear in stating what the use of the questionnaire will achieve. For example, it may want to compare two different groups, two different interventions or change over time amongst the same group<sup>52</sup>. The studies that were identified during the literature search were all specifically regarding women's experiences on contraception, for a variety of different reasons. Therefore, they would have all benefitted from the use of a specific questionnaire that assesses the known effects of contraception.

#### *4.4 Conclusion*

This study explored the ways in which we measure the QoL of women using contraception. Through an extensive literature search, it was discovered that there are, in fact, two questionnaires in use; the ORTHO BC-SAT and the SEC-QOL, that have been validated for the use of assessing the satisfaction or QoL, respectively, of women using contraception. One hundred and eleven studies were identified as using a questionnaire in the setting of assessing HRQOL in relation to contraception. However, it was interesting to find that the general HRQOL instruments were used far more frequently than the contraception specific ones. The SF-36, the Moos MDQ, the Becks Depression Inventory and the EQ-5D were used a combined total of 65 times (38%), whereas the ORTHO BC-SAT and the SEC-QOL were used a combined number of six (0.03%).

This study concludes that there are two measures in circulation which assess either satisfaction (ORTHO BC-SAT) or QoL (SEC-QOL) of women using contraception. These tools could be used to assess the QoL of women using contraception and are more beneficial than using generic HRQOL measures such as the SF-36 or the EQ-5D. However, there is room for an alternative and

improved measure that is based on a British population and that includes pertinent questions about sexual QoL, mental health and menstrual symptoms.

## 5.0 References

1. Calman KC. Quality of life in cancer patients--an hypothesis. *J Med Ethics* 1984;10(3):124-7.
2. Bakas T, McLennon SM, Carpenter JS, Buelow JM, Otte JL, Hanna KM, et al. Systematic review of health-related quality of life models. *Health Qual Life Outcomes* 2012;10:134.
3. Research USDoHaHSFCfDEa, Research USDoHaHSFCfBEa, Health. USDoHaHSFCfDaR. Guidance for industry: patient-reported outcome measures: use in medical product development to support labeling claims: draft guidance. In: *Health Qual Life Outcomes*. 2006/10/13 ed; 2006. p. 79.
4. Hanmer J, Feeny D, Fischhoff B, Hays RD, Hess R, Pilkonis PA, et al. The PROMIS of QALYs. *Health Qual Life Outcomes* 2015;13:122.
5. Ferrans CE, Zerwic JJ, Wilbur JE, Larson JL. Conceptual model of health-related quality of life. *J Nurs Scholarsh* 2005;37(4):336-42.
6. Ware JE, Jr., Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Med Care* 1992;30(6):473-83.
7. Devlin NJ, Brooks R. EQ-5D and the EuroQol Group: Past, Present and Future. *Appl Health Econ Health Policy* 2017;15(2):127-137.
8. Beck AT, Ward CH, Mendelson M, Mock J, Erbaugh J. An inventory for measuring depression. *Arch Gen Psychiatry* 1961;4:561-71.
9. Lundgren-Nilsson Å, Jonsdottir IH, Ahlborg G, Tennant A. Construct validity of the psychological general well being index (PGWBI) in a sample of patients undergoing treatment for stress-related exhaustion: a rasch analysis. In: *Health Qual Life Outcomes*; 2013. p. 2.
10. Saxena S, Carlson D, Billington R. The WHO quality of life assessment instrument (WHOQOL-Bref): the importance of its items for cross-cultural research. *Qual Life Res* 2001;10(8):711-21.
11. Hunter MS. The Women's Health Questionnaire (WHQ): Frequently Asked Questions (FAQ). In: *Health Qual Life Outcomes*; 2003. p. 41.
12. Davison SL, Bell RJ, LaChina M, Holden SL, Davis SR. The relationship between self-reported sexual satisfaction and general well-being in women. *J Sex Med* 2009;6(10):2690-7.
13. Gallicchio L, Schilling C, Tomic D, Miller SR, Zacur H, Flaws JA. Correlates of sexual functioning among mid-life women. *Climacteric* 2007;10(2):132-42.
14. Meston CM. Validation of the Female Sexual Function Index (FSFI) in Women with Female Orgasmic Disorder and in Women with Hypoactive Sexual Desire Disorder. *J Sex Marital Ther* 2003;29(1):39-46.
15. Burrows LJ, Basha M, Goldstein AT. The effects of hormonal contraceptives on female sexuality: a review. *J Sex Med* 2012;9(9):2213-23.
16. Sanders SA, Graham CA, Bass JL, Bancroft J. A prospective study of the effects of oral contraceptives on sexuality and well-being and their relationship to discontinuation. *Contraception* 2001;64(1):51-8.

17. Maasoumi R, Lamyian M, Montazeri A, Azin SA, Aguilar-Vafaie ME, Hajizadeh E. The sexual quality of life-female (SQOL-F) questionnaire: translation and psychometric properties of the Iranian version. *Reprod Health* 2013;10:25.
18. Symonds T, Boolell M, Quirk F. Development of a questionnaire on sexual quality of life in women. *J Sex Marital Ther* 2005;31(5):385-97.
19. Thirlaway K, Fallowfield L, Cuzick J. The Sexual Activity Questionnaire: a measure of women's sexual functioning. *Qual Life Res* 1996;5(1):81-90.
20. Palmer S, Byford S, Raftery J. Economics notes: types of economic evaluation. *Bmj* 1999;318(7194):1349.
21. Mavranезouli I. Health economics of contraception. *Best Pract Res Clin Obstet Gynaecol* 2009;23(2):187-98.
22. Sassi F. Calculating QALYs, comparing QALY and DALY calculations. *Health Policy Plan* 2006;21(5):402-8.
23. Bailey J, Mann S, Wayal S, Hunter R, Free C, Abraham C, et al. Health economic evaluations in sexual health promotion delivered by digital media. 2015.
24. Whitehead SJ, Ali S. Health outcomes in economic evaluation: the QALY and utilities. *Br Med Bull* 2010;96:5-21.
25. United Nations DoEaSA, Population Division. Trends in Contraceptive Use Worldwide 2015 (ST/ESA/SER.A/349). In; 2015.
26. Ahmed S, Li Q, Liu L, Tsui AO. Maternal deaths averted by contraceptive use: an analysis of 172 countries. *Lancet* 2012;380(9837):111-25.
27. Roach RE, Helmerhorst FM, Lijfering WM, Stijnen T, Algra A, Dekkers OM. Combined oral contraceptives: the risk of myocardial infarction and ischemic stroke. *Cochrane Database Syst Rev* 2015(8):Cd011054.
28. Lee J, Jezewski MA. Attitudes toward oral contraceptive use among women of reproductive age: a systematic review. *ANS Adv Nurs Sci* 2007;30(1):E85-103.
29. Fuchs N, Prinz H, Koch U. Attitudes to current oral contraceptive use and future developments: the women's perspective. *Eur J Contracept Reprod Health Care* 1996;1(3):275-84.
30. Gallo MF, Lopez LM, Grimes DA, Carayon F, Schulz KF, Helmerhorst FM. Combination contraceptives: effects on weight. *Cochrane Database Syst Rev* 2014(1):Cd003987.
31. Dragoman MV. The combined oral contraceptive pill -- recent developments, risks and benefits. *Best Pract Res Clin Obstet Gynaecol* 2014;28(6):825-34.
32. Lawrie TA, Helmerhorst FM, Maitra NK, Kulier R, Bloemenkamp K, Gulmezoglu AM. Types of progestogens in combined oral contraception: effectiveness and side-effects. *Cochrane Database Syst Rev* 2011(5):Cd004861.
33. Coney P, Washenik K, Langley RG, DiGiovanna JJ, Harrison DD. Weight change and adverse event incidence with a low-dose oral contraceptive: two randomized, placebo-controlled trials. *Contraception* 2001;63(6):297-302.
34. Percy L. The new UK Medical Eligibility Criteria (UKMEC): what has changed? *J Fam Plann Reprod Health Care* 2016;42(2):81-2.
35. Warhurst S, Roife CJ, Brew BJ, Bateson D, McGeechan K, Merki-Feld GS, et al. Effectiveness of the progestin-only pill for migraine treatment in women: A systematic review and meta-analysis. *Cephalalgia* 2017;333102417710636.

36. Lopez LM, Ramesh S, Chen M, Edelman A, Otterness C, Trussell J, et al. Progestin-only contraceptives: effects on weight. *Cochrane Database Syst Rev* 2016(8):Cd008815.
37. Lahteenmaki P, Rauramo I, Backman T. The levonorgestrel intrauterine system in contraception. *Steroids* 2000;65(10-11):693-7.
38. Orbo A, Vereide A, Arnes M, Pettersen I, Straume B. Levonorgestrel-impregnated intrauterine device as treatment for endometrial hyperplasia: a national multicentre randomised trial. *Bjog* 2014;121(4):477-86.
39. Prileszky G, Kai J, Gupta J. Mirena coil for heavy menstrual bleeding. *Br J Gen Pract* 2008;58(557):886; author reply 886-7.
40. Hubacher D, Chen PL, Park S. Side effects from the copper IUD: do they decrease over time? *Contraception* 2009;79(5):356-62.
41. Peipert JF, Zhao Q, Allsworth JE, Petrosky E, Madden T, Eisenberg D, et al. Continuation and Satisfaction of Reversible Contraception. *Obstet Gynecol* 2011;117(5):1105-13.
42. Aoun J, Dines VA, Stovall DW, Mete M, Nelson CB, Gomez-Lobo V. Effects of age, parity, and device type on complications and discontinuation of intrauterine devices. *Obstet Gynecol* 2014;123(3):585-92.
43. Madden T, McNicholas C, Zhao Q, Secura GM, Eisenberg DL, Peipert JF. Association of Age and Parity With Intrauterine Device Expulsion. *Obstet Gynecol* 2014;124(4):718-26.
44. Hubacher D. Copper intrauterine device use by nulliparous women: review of side effects. *Contraception* 2007;75(6 Suppl):S8-11.
45. Turok DK, Jacobson JC, Dermish AI, Simonsen SE, Gurtcheff S, McFadden M, et al. Emergency contraception with a copper IUD or oral levonorgestrel: an observational study of 1-year pregnancy rates. *Contraception* 2014;89(3):222-8.
46. Gezginc K, Balci O, Karatayli R, Colakoglu MC. Contraceptive efficacy and side effects of Implanon. *Eur J Contracept Reprod Health Care* 2007;12(4):362-5.
47. Blumenthal PD, Gemzell-Danielsson K, Marintcheva-Petrova M. Tolerability and clinical safety of Implanon. *Eur J Contracept Reprod Health Care* 2008;13 Suppl 1:29-36.
48. Hoggart L, Newton VL. Young women's experiences of side-effects from contraceptive implants: a challenge to bodily control. *Reprod Health Matters* 2013;21(41):196-204.
49. Westhoff C. Depot-medroxyprogesterone acetate injection (Depo-Provera): a highly effective contraceptive option with proven long-term safety. *Contraception* 2003;68(2):75-87.
50. Bahamondes L, Del Castillo S, Tabares G, Arce XE, Perrotti M, Petta C. Comparison of weight increase in users of depot medroxyprogesterone acetate and copper IUD up to 5 years. *Contraception* 2001;64(4):223-5.
51. Bahamondes L, Valeria Bahamondes M, Shulman LP. Non-contraceptive benefits of hormonal and intrauterine reversible contraceptive methods. *Hum Reprod Update* 2015;21(5):640-51.
52. Aaronson N, Alonso J, Burnam A, Lohr KN, Patrick DL, Perrin E, et al. Assessing health status and quality-of-life instruments: attributes and review criteria. *Qual Life Res* 2002;11(3):193-205.
53. Lord FM, Novick MR. *Statistical Theories of Mental Scores.*: Addison-Wesley Publishing Company; 1968.



54. Güler N, Uyanık GK, Teker GT. Comparison of classical test theory and item response theory in terms of item parameters. *EJRE* 2014;2(1):1-6.
55. Hays RD, Morales LS, Reise SP. Item Response Theory and Health Outcomes Measurement in the 21st Century. *Med Care* 2000;38(9 Suppl):II28-42.
56. Heo M, Kim N, Faith MS. Statistical power as a function of Cronbach alpha of instrument questionnaire items. *BMC Med Res Methodol* 2015;15.
57. Mokkink LB, Terwee CB, Knol DL, Stratford PW, Alonso J, Patrick DL, et al. Protocol of the COSMIN study: Consensus-based Standards for the selection of health Measurement INstruments. *BMC Med Res Methodol* 2006;6:2.
58. Mokkink LB, Terwee CB, Knol DL, Stratford PW, Alonso J, Patrick DL, et al. The COSMIN checklist for evaluating the methodological quality of studies on measurement properties: a clarification of its content. *BMC Med Res Methodol* 2010;10:22.
59. Presser S, Couper MP, Lessler JT, Martin E, Martin J, Rothgeb JM, et al. Methods for Testing and Evaluating Survey Questions *Public Opinion Quarterly* 2004;68(1):109-130.
60. Graesslin O, Barjot P, Hoffet M, Cohen D, Vaillant P, Clerson P. The EVAPIL scale, a new tool to assess tolerance of oral contraceptives. *Contraception* 2009;80(6):540-54.
61. Novak A, de la Loge C, Abetz L. Development and validation of an acceptability and satisfaction questionnaire for a contraceptive vaginal ring, NuvaRing. *Pharmacoeconomics* 2004;22(4):245-56.
62. Lukes AS, Reardon B, Arepally G. Use of the levonorgestrel-releasing intrauterine system in women with hemostatic disorders. *Fertil Steril* 2008;90(3):673-7.
63. Bitzer J, Tschudin S, Meier-Burgoa J, Armbruster U, Schwendke A. [Effects on the quality of life of a new oral contraceptive containing 30 mcg EE and 3 mg drospirenone (Yasmin)]. *Praxis (Bern 1994)* 2003;92(25-26):1177-84.
64. Colwell HH, Mathias SD, Cimms TA, Rothman M, Friedman AJ, Patrick DL. The ORTHO BC-SAT--a satisfaction questionnaire for women using hormonal contraceptives. *Qual Life Res* 2006;15(10):1621-31.
65. Mathias SD, Colwell HH, Cimms T, Karvois DL, LoCoco JM, Friedman AJ. Measuring Satisfaction with Hormonal Contraceptives: A Conceptual Framework for a Generic Measure of Satisfaction. *Quality of Life Research* 2003:802-802.
66. Mathias S, LoCoco J, Karvois D, Colwell H, Cimms T, Friedman, et al. The Ortho Birth Control Satisfaction Assessment Tool (Ortho BC-SAT): Reliability and Validity of a New Satisfaction Questionnaire. *Qual Life Res* 2004;13(9):1548.
67. Mosher WD, Martinez GM, Chandra A, Abma JC, Willson SJ. Use of contraception and use of family planning services in the United States: 1982-2002. *Adv Data* 2004(350):1-36.
68. Perez-Campos E, Duenas JL, de la Viuda E, Gomez MA, Lertxundi R, Sanchez-Borrego R, et al. Development and validation of the SEC-QOL questionnaire in women using contraceptive methods. *Value Health* 2011;14(6):892-9.
69. Cristobal I, Lete LI, Viuda Ede L, Perulero N, Arbat A, Canals I. One year quality of life measured with SEC-QoL in levonorgestrel 52 mg IUS users. *Contraception* 2016;93(4):367-71.

70. Gupta J, Kai J, Middleton L, Pattison H, Gray R, Daniels J. Levonorgestrel intrauterine system versus medical therapy for menorrhagia. *N Engl J Med* 2013;368(2):128-37.
71. Gupta JK, Daniels JP, Middleton LJ, Pattison HM, Prileszky G, Roberts TE, et al. Outcome measures for the evaluation of treatment of heavy menstrual bleeding. 2015.
72. Moos RH. The development of a menstrual distress questionnaire. *Psychosom Med* 1968;30(6):853-67.
73. Ross C, Coleman G, Stojanovska C. Factor structure of the modified Moos Menstrual Distress Questionnaire: assessment of prospectively reported follicular, menstrual and premenstrual symptomatology. *J Psychosom Obstet Gynaecol* 2003;24(3):163-74.
74. Hawes E, Oei TPS. The menstrual distress questionnaire: Are the critics right? *Curr Psychol* 1990;11(3):264-281.
75. Kelly S, Davies E, Fearn S, McKinnon C, Carter R, Gerlinger C, et al. Effects of oral contraceptives containing ethinylestradiol with either drospirenone or levonorgestrel on various parameters associated with well-being in healthy women: a randomized, single-blind, parallel-group, multicentre study. *Clin Drug Investig* 2010;30(5):325-36.
76. EuroQol--a new facility for the measurement of health-related quality of life. *Health Policy* 1990;16(3):199-208.
77. Whynes DK. Correspondence between EQ-5D health state classifications and EQ VAS scores. *Health Qual Life Outcomes* 2008;6:94.
78. Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20(10):1727-36.

## 6.0 Appendix

### 6.1 Search Protocol

1	exp Contraception/	25201
2	birth control.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	4952
3	Contracept*.mp.	86637
4	exp Contraceptive agents/	68430
5	exp Contraceptive agents, female/	62566
6	combined pill.mp.	152
7	((oest* and prog*) adj3 (pill or contracept*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	372
8	exp contraceptives, oral/	44955
9	mini pill.mp.	73
10	(contracept* adj4 estradiol).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	532
11	(progest* adj4 (contracept* or pill*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	5409
12	exp contraceptive devices/	23896
13	mirena.mp.	276
14	intrauterine device.mp.	3820
15	intrauterine system.mp.	972
16	IUD.mp.	7521
17	IUS.mp.	1015
18	LARC.mp.	1018
19	LNG-IUS.mp.	627
20	exp Norpregnanes/	20682

21	(contracept* adj3 (inject* or implan*)).mp. [mp=title, abstract, original title, name of substance word,2672 subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	
22	etonogestrel implant.mp.	105
23	nexplanon.mp. [mp=title, abstract, original title, name of substance word, subject heading word,48 keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	
24	(Medroxyprogesterone Acetate adj4 contracept*).mp. [mp=title, abstract, original title, name of417 substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	
25	(Depo-provera adj4 contracept*).mp. [mp=title, abstract, original title, name of substance word,247 subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	
26	((transdermal or patch*) adj3 contracept*).mp. [mp=title, abstract, original title, name of substance338 word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	
27	(vagina* ring adj4 contracept*).mp. [mp=title, abstract, original title, name of substance word, subject249 heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	
28	withdrawal method.mp.	74
29	abortion.mp.	83272
30	exp abortion, induced/	39161
31	termination of pregnancy.mp.	5452
32	Pregnancy, Unwanted/	2568
33	Pregnancy, Unplanned/	1435
34	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or211664 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33	
35	"Quality of Life"/	157788
36	(qol or HRQOL).mp.	41123

37	(qualit* adj3 (life or lives)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	282055
38	exp emotions/	209229
39	Satisfaction.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	173038
40	personal satisfaction/	15510
41	((sex or sexual) adj3 (pleasur* or satisf* or dissatisf* or dysfunction*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	21331
42	relationship satisfaction.mp.	1155
43	exp sexual dysfunctions, psychological/	24228
44	Libido/	4618
45	35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44	653287
46	"Outcome Assessment (Health Care)"/	63085
47	Treatment outcome/	830067
48	exp "Surveys and Questionnaires"/	869190
49	(survey* or question* or interview* or evaluat* or measur* or outcome* or assess* form or forms).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	7972380
50	Risk assessment.mp.	249108
51	exp risk assessment/	225402
52	Health Knowledge, Attitudes, Practice/	94611
53	46 or 47 or 48 or 49 or 50 or 51 or 52	8238790
54	34 and 45 and 53	4471
55	exp Animals/ not Humans/	4440485
56	54 not 55	

## 6.2 Female Sexual Function Index (FSFI)

Subject Identifier \_\_\_\_\_

Date \_\_\_\_\_

**INSTRUCTIONS:** These questions ask about your sexual feelings and responses during the past 4 weeks. Please answer the following questions as honestly and clearly as possible. Your responses will be kept completely confidential. In answering these questions the following definitions apply:

Sexual activity can include caressing, foreplay, masturbation and vaginal intercourse.

Sexual intercourse is defined as penile penetration (entry) of the vagina.

Sexual stimulation includes situations like foreplay with a partner, self-stimulation (masturbation), or sexual fantasy.

### **CHECK ONLY ONE BOX PER QUESTION.**

Sexual desire or interest is a feeling that includes wanting to have a sexual experience, feeling receptive to a partner's sexual initiation, and thinking or fantasizing about having sex.

1. Over the past 4 weeks, how **often** did you feel sexual desire or interest?

- ☐ Almost always or always
- ☐ Most times (more than half the time)
- ☐ Sometimes (about half the time)
- ☐ A few times (less than half the time)
- ☐ Almost never or never

2. Over the past 4 weeks, how would you rate your **level** (degree) of sexual desire or interest?

- ☐ Very high
- ☐ High
- ☐ Moderate
- ☐ Low
- ☐ Very low or none at all

Sexual arousal is a feeling that includes both physical and mental aspects of sexual excitement. It may include feelings of warmth or tingling in the genitals, lubrication (wetness), or muscle contractions.

3. Over the past 4 weeks, how **often** did you feel sexually aroused ("turned on") during sexual activity or intercourse?

- ☐ No sexual activity
- ☐ Almost always or always
- ☐ Most times (more than half the time)
- ☐ Sometimes (about half the time)
- ☐ A few times (less than half the time)
- ☐ Almost never or never

4. Over the past 4 weeks, how would you rate your **level** of sexual arousal ("turn on") during sexual activity or intercourse?

- ☐ No sexual activity
- ☐ Very high
- ☐ High
- ☐ Moderate
- ☐ Low
- ☐ Very low or none at all

5. Over the past 4 weeks, how **confident** were you about becoming sexually aroused during sexual activity or intercourse?

- ☐ No sexual activity
- ☐ Very high confidence
- ☐ High confidence
- ☐ Moderate confidence
- ☐ Low confidence
- ☐ Very low or no confidence

6. Over the past 4 weeks, how **often** have you been satisfied with your arousal (excitement) during sexual activity or intercourse?

- ☐ No sexual activity
- ☐ Almost always or always
- ☐ Most times (more than half the time)
- ☐ Sometimes (about half the time)
- ☐ A few times (less than half the time)
- ☐ Almost never or never

7. Over the past 4 weeks, how **often** did you become lubricated ("wet") during sexual activity or intercourse?

- ☐ No sexual activity
- ☐ Almost always or always
- ☐ Most times (more than half the time)
- ☐ Sometimes (about half the time)
- ☐ A few times (less than half the time)
- ☐ Almost never or never

8. Over the past 4 weeks, how **difficult** was it to become lubricated ("wet") during sexual activity or intercourse?

- ☐ No sexual activity
- ☐ Extremely difficult or impossible
- ☐ Very difficult
- ☐ Difficult
- ☐ Slightly difficult
- ☐ Not difficult

9. Over the past 4 weeks, how often did you **maintain** your lubrication ("wetness") until completion of sexual activity or intercourse?

- ☐ No sexual activity
- ☐ Almost always or always
- ☐ Most times (more than half the time)
- ☐ Sometimes (about half the time)
- ☐ A few times (less than half the time)
- ☐ Almost never or never

10. Over the past 4 weeks, how **difficult** was it to maintain your lubrication ("wetness") until completion of sexual activity or intercourse?

- ☐ No sexual activity
- ☐ Extremely difficult or impossible
- ☐ Very difficult
- ☐ Difficult
- ☐ Slightly difficult
- ☐ Not difficult



11. Over the past 4 weeks, when you had sexual stimulation or intercourse, how **often** did you reach orgasm (climax)?

- ☐ No sexual activity
- ☐ Almost always or always
- ☐ Most times (more than half the time)
- ☐ Sometimes (about half the time)
- ☐ A few times (less than half the time)
- ☐ Almost never or never

12. Over the past 4 weeks, when you had sexual stimulation or intercourse, how **difficult** was it for you to reach orgasm (climax)?

- ☐ No sexual activity
- ☐ Extremely difficult or impossible
- ☐ Very difficult
- ☐ Difficult
- ☐ Slightly difficult
- ☐ Not difficult

13. Over the past 4 weeks, how **satisfied** were you with your ability to reach orgasm (climax) during sexual activity or intercourse?

- ☐ No sexual activity
- ☐ Very satisfied
- ☐ Moderately satisfied
- ☐ About equally satisfied and dissatisfied
- ☐ Moderately dissatisfied
- ☐ Very dissatisfied

14. Over the past 4 weeks, how **satisfied** have you been with the amount of emotional closeness during sexual activity between you and your partner?

- ☐ No sexual activity
- ☐ Very satisfied
- ☐ Moderately satisfied
- ☐ About equally satisfied and dissatisfied
- ☐ Moderately dissatisfied
- ☐ Very dissatisfied

15. Over the past 4 weeks, how **satisfied** have you been with your sexual relationship with your partner?

- ☐ Very satisfied
- ☐ Moderately satisfied
- ☐ About equally satisfied and dissatisfied
- ☐ Moderately dissatisfied
- ☐ Very dissatisfied

16. Over the past 4 weeks, how **satisfied** have you been with your overall sexual life?

- ☐ Very satisfied
- ☐ Moderately satisfied
- ☐ About equally satisfied and dissatisfied
- ☐ Moderately dissatisfied
- ☐ Very dissatisfied

17. Over the past 4 weeks, how **often** did you experience discomfort or pain during vaginal penetration?

- ☐ Did not attempt intercourse
- ☐ Almost always or always
- ☐ Most times (more than half the time)
- ☐ Sometimes (about half the time)
- ☐ A few times (less than half the time)
- ☐ Almost never or never

18. Over the past 4 weeks, how **often** did you experience discomfort or pain following vaginal penetration?

- ☐ Did not attempt intercourse
- ☐ Almost always or always
- ☐ Most times (more than half the time)
- ☐ Sometimes (about half the time)
- ☐ A few times (less than half the time)
- ☐ Almost never or never

19. Over the past 4 weeks, how would you rate your **level** (degree) of discomfort or pain during or following vaginal penetration?

- ☐ Did not attempt intercourse
- ☐ Very high
- ☐ High
- ☐ Moderate
- ☐ Low
- ☐ Very low or none at all

***Thank you for completing this questionnaire***

## The NuvaRing Acceptability Questionnaire

### NuvaRing® Acceptability Questionnaire

**Instructions:** Please read the questions carefully and tick the right box(es). There is no right or wrong answer. You just have to indicate by marking the appropriate box what you have experienced and felt.

1. Could the ring easily be inserted?  
☐ Never ☐ Rarely ☐ Occasionally ☐ Frequently ☐ Always
2. Could the ring easily be removed?  
☐ Never ☐ Rarely ☐ Occasionally ☐ Frequently ☐ Always
3. Has the ring been removed in the ring-period?  
☐ Never ☐ Rarely ☐ Occasionally ☐ Frequently ☐ Always
4. When you removed the ring in the ring-period, has the ring been stored in the sachet?  
☐ Never ☐ Rarely ☐ Occasionally ☐ Frequently ☐ Always  
☐ Not applicable; ring has not been removed during the ring-period
5. Please indicate the reasons why the ring has been removed during the ring-period: (please tick all boxes which apply)  
☐ Uncomfortable  
☐ Bleeding – spotting  
☐ Interference with intercourse  
☐ Falling out of the ring  
☐ Not applicable; ring has not been removed during the ring-period  
☐ Other, specify: \_\_\_\_\_
6. The instruction was adequate to remember when the ring should be inserted or removed:  
☐ Strongly agree ☐ Agree ☐ Undecided ☐ Disagree  
☐ Strongly disagree
7. You are satisfied with using the ring:  
☐ Strongly agree ☐ Agree ☐ Undecided ☐ Disagree  
☐ Strongly disagree
8. Could you feel the ring during the intercourse?  
☐ Never ☐ Rarely ☐ Occasionally ☐ Frequently ☐ Always
9. Could the ring be felt by the partner during intercourse?  
☐ Never ☐ Rarely ☐ Occasionally ☐ Frequently ☐ Always
10. Did the partner mind that you were using the ring?  
☐ Never ☐ Rarely ☐ Occasionally ☐ Frequently ☐ Always
11. Did the length of the menstrual period change in comparison with the last used method?  
☐ Much shorter ☐ Shorter ☐ Same ☐ Longer ☐ Much longer
12. Did the menstrual pain change in comparison with the last used method?  
☐ Much less ☐ Less ☐ Same ☐ More ☐ Much more

**Instructions:** Please fill out the questions 13 and 14 by putting a number in the box: 1 = most important feature, 2 = next most importance feature, 3 = subsequent most important feature.

13. Please indicate your top three reasons ranked by personal preference for liking the ring:  
☐ Not applicable because you do not like the ring  
☐ Bleeding – spotting pattern  
☐ Do not have to remember anything  
☐ Considered a more natural method  
☐ No interference with intercourse  
☐ Easy to use  
☐ Is not messy  
☐ User does not feel the ring  
☐ Considered an effective method  
☐ Other, specify: \_\_\_\_\_
14. Please indicate your top three reasons ranked by personal preference for disliking the ring:  
☐ Not applicable because you do like the ring  
☐ Bleeding – spotting pattern  
☐ Interference with intercourse  
☐ Falling out of the ring  
☐ Uncomfortable  
☐ Other, specify: \_\_\_\_\_

**Instructions:** Please fill out the following questions by ticking the right box(es).

15. Best method in your opinion for family planning is:  
☐ Ring ☐ Foam – Condom – Diaphragm ☐ IUD  
☐ Oral contraceptives  
☐ Other, specify: \_\_\_\_\_
16. You would recommend this method to others:  
☐ Strongly agree ☐ Agree ☐ Undecided ☐ Disagree  
☐ Strongly disagree
17. The method of removal of the ring from the sealed sachet is clear:  
☐ Strongly agree ☐ Agree ☐ Undecided ☐ Disagree  
☐ Strongly disagree
18. It is easy to open the sachet:  
☐ Strongly agree ☐ Agree ☐ Undecided ☐ Disagree  
☐ Strongly disagree
19. It is clear that the ring should be put back in the sachet after use:  
☐ Strongly agree ☐ Agree ☐ Undecided ☐ Disagree  
☐ Strongly disagree
20. It is easy to store the ring: (i.e. open the empty sachet, put the ring in the sachet and reclose it)  
☐ Strongly agree ☐ Agree ☐ Undecided ☐ Disagree  
☐ Strongly disagree
21. It is clear why the sachet should be used to store the ring after the ring has been used:  
☐ Strongly agree ☐ Agree ☐ Undecided ☐ Disagree  
☐ Strongly disagree

### Literature Search Results

Title	Author/Reference	Tool Used
<b>A Canadian multicentre prospective study on the effects of an oral contraceptive containing 3 mg drospirenone and 30 microg ethinyl oestradiol on somatic and psychological symptoms related to water retention and on body weight.</b>	Endrikat, Jan; Sandri, Mirella; Gerlinger, Christoph; Rubig, Alexander; Schmidt, Werner; Fortier Christoph The European Journal of Contraception and Reproductive Health Care // 2007;12(3):220-228	Moos MDS
<b>A clinical study assessing the efficacy of a new variant of the levonorgestrel intrauterine system for abnormal uterine bleeding.</b>	Gopimohan, Rajmohan; Chandran, Amrutha; Jacob, Joyce; Bhaskar, Sunil; Aravindhakshan, Rajeev; Aprem, Abi S International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics // 2015;129(2):114-117	EQ-5D-3L
<b>A comparative study on satisfaction from hormonal contraceptives: depot medroxyprogesterone acetate (DMPA), Cyclofem and LD.</b>	Fathizadeh, Nahid; Abdi, Fatemeh; Savabi, Mitra Iranian journal of nursing and midwifery research // 2011;16(4):304-308	ORTHO BC-SAT
<b>A comparison of cycle control and effect on well-being of monophasic gestodene-, triphasic gestodene- and monophasic desogestrel-containing oral contraceptives. Gestodene Study Group.</b>	Bruni, V; Croxatto, H; De La Cruz, J; Dhont, M; Durlot, F; Fernandes, M T; Andrade, R P; Weisberg, E; Rhoa, M Gynecological endocrinology : the official journal of the International Society of Gynecological Endocrinology // 2000;14(2):90-98	modified Moos Menstrual Distress Questionnaire
<b>A first-choice combined oral contraceptive influences general well-being in healthy women: a double-blind, randomized, placebo-controlled trial.</b>	Zethraeus, Niklas; Dreber, Anna; Ranehill, Eva; Blomberg, Liselott; Labrie, Fernand; von Schoultz, Bo; Johannesson, Magnus; Hirschberg, Angelica Linden Fertility and sterility // 2017;107(5):1238-1245	Psychological General Well-Being Index (PGWBI) and the Beck Depression Inventory (BDI);

<b>A new monophasic oral contraceptive containing drospirenone. Effect on premenstrual symptoms.</b>	Brown, Candace; Ling, Frank; Wan, Jim The Journal of reproductive medicine // 2002;47(1):14-22	Womens Health Assessment Questionnaire
<b>A prospective follow-up of two 21/7 cycles followed by two extended regimen 84/7 cycles with contraceptive pills containing ethinyl estradiol and drospirenone.</b>	Seidman, Daniel S; Yeshaya, Arie; Ber, Amos; Amodai, Ida; Feinstein, Itzhak; Finkel, Israelit; Gordon, Nina; Porat, Noga; Samuel, Dganit; Shiran-Makler, Einat; Wolman, Igal The Israel Medical Association journal : IMAJ // 2010;12(7):400-405	PGWBI
<b>A prospective study of the effects of the progestagen content of oral contraceptives on measures of affect, automatization, and perceptual restructuring ability.</b>	Worsley, A Psychopharmacology // 1980;67(3):289-296	Profile of Mood States
<b>A randomised controlled trial of the clinical effectiveness and cost-effectiveness of the levonorgestrel-releasing intrauterine system in primary care against standard treatment for menorrhagia: the ECLIPSE trial.</b>	Gupta, Janesh K; Daniels, Jane P; Middleton, Lee J; Pattison, Helen M; Prileszky, Gail; Roberts, Tracy E; Sanghera, Sabina; Barton, Pelham; Gray, Richard; Kai, Joe; Group, ECLIPSE Collaborative Health technology assessment (Winchester, England) // 2015;19(88):i-118	Menorrhagia Multi-Attribute Scale (MMAS) European Quality of Life-5 Dimensions (EQ-5D) and the Short Form questionnaire-6 Dimensions (SF-6D)
<b>A randomised trial comparing the levonorgestrel intrauterine system and thermal balloon ablation for heavy menstrual bleeding.</b>	Busfield, R A; Farquhar, C M; Sowter, M C; Lethaby, A; Sprecher, M; Yu, Y; Sadler, L C; Brown, P; Johnson, N BJOG : an international journal of obstetrics and gynaecology // 2006;113(3):257-263	SF-36
<b>A randomized crossover study of medroxyprogesterone acetate and Diane-35 in adolescent girls with polycystic ovarian syndrome.</b>	Chung, Jacqueline P W; Yiu, Alice K W; Chung, Tony K H; Chan, Symphorosa S C Journal of pediatric and adolescent gynecology // 2014;27(3):166-171	Short Form-36 score

<b>Added benefits of drospirenone for compliance</b>	Foidart J.-M. Climacteric // 2005;8(SUPPL. 3):28-34	Women's Health Questionnaire (review of other studies)
<b>Adolescents' experiences using the contraceptive patch versus pills.</b>	Sucato, Gina S; Land, Stephanie R; Murray, Pamela J; Cecchini, Reena; Gold, Melanie A Journal of pediatric and adolescent gynecology // 2011;24(4):197-203	Youth Quality of Life instrument
<b>An assessment of psychological state associated with the menstrual cycle in users of oral contraception.</b>	Marriott, Alison; Faragher, E B Journal of Psychosomatic Research // 1986;30(1):41-47	Menstrual Distress Questionnaire
<b>An evaluation of depression as a side effect of oral contraceptives</b>	Lewis, A; Hoghughi, M The British journal of psychiatry : the journal of mental science // 1969;115(523):697-701	Hamilton rating Score
<b>Anxiety and depression in women with intrauterine device (IUD) and sterilized: A comparative study.</b>	Luo, Lin; Wu, Shizhong; Zhu, Changming; Fan, Qifu; Liu, Keqiang; Sun, Guoliang Chinese Mental Health Journal // 1998;12(3):134-135	Self-Rating Anxiety Scale, Self-Rating Depression Scale, and the Eysenck Personality Questionnaire (EPQ)
<b>Assessment of country-level health-related quality of life (HRQL) outcomes and treatment effect of levonorgestrel-releasing intrauterine system (LNG-IUS) in women with idiopathic menorrhagia</b>	D.E., Stull; D., Vanness; D., Lambrelli; A., Filonenko; E., Franke; , Wittrup-Jensen K Value in Health // 2011;14(7):A406-A406	Physical and Mental component summaries (PCS and MCS) of the SF-36v2
<b>Associations between recent contraceptive use and quality of life among women</b>	S.L., Williams; S.M., Parisi; R., Hess; , Schwarz E B Contraception ;():	RAND-36
<b>Associations between recent contraceptive use and quality of life among women.</b>	Williams, Sanithia L; Parisi, Sara M; Hess, Rachel; Schwarz, E Bimla Contraception // 2012;85(3):282-287	RAND-36

<b>Clinical outcomes and costs with the levonorgestrel-releasing intrauterine system or hysterectomy for treatment of menorrhagia: randomized trial 5-year follow-up.</b>	Hurskainen, Ritva; Teperi, Juha; Rissanen, Pekka; Aalto, Anna-Mari; Grenman, Seija; Kivela, Aarre; Kujansuu, Erkki; Vuorma, Sirkku; Yliskoski, Merja; Paavonen, Jorma JAMA // 2004;291(12):1456-1463	5-Dimensional EuroQol and the RAND 36-Item Short-Form
<b>Combined oral contraceptive use is associated with both improvement and worsening of mood in the different phases of the treatment cycle-A double-blind, placebo-controlled randomized trial.</b>	Lundin, Cecilia; Danielsson, Kristina Gemzell; Bixo, Marie; Moby, Lena; Bengtsdotter, Hanna; Jawad, Izabella; Marions, Lena; Brynhildsen, Jan; Malmborg, Agota; Lindh, Ingela; Poromaa, Inger Sundstrom Psychoneuroendocrinology // 2017;76():135-143	Daily Record of Severity of Problems (DRSP)
<b>Comparative effectiveness and impact on health-related quality of life of hysterectomy vs. levonorgestrel intra-uterine system for abnormal uterine bleeding.</b>	Cozza, G; Pinto, A; Giovanale, V; Bianchi, P; Guarino, A; Marziani, R; Frega, A; Caserta, D European review for medical and pharmacological sciences // 2017;21(9):2255-2260	5-Dimensional Euro Qol (EQ-5D),
<b>Comparative, open-label prospective study on the quality of life and sexual function of women affected by endometriosis-associated pelvic pain on 2 mg dienogest/30 micro g ethinyl estradiol continuous or 21/7 regimen oral contraceptive.</b>	Caruso, S; Iraci, M; Cianci, S; Fava, V; Casella, E; Cianci, A Journal of endocrinological investigation // 2016;39(8):923-931	The Short Form-36, Female Sexual Function Index (FSFI) and the Female Sexual Distress Scale (FSDS)
<b>Comparison of levonorgestrel intrauterine system versus hysterectomy on efficacy and quality of life in patients with adenomyosis.</b>	Ozdegirmenci, Ozlem; Kayikcioglu, Fulya; Akgul, Mehmet Akif; Kaplan, Metin; Karcaaltincaba, Musturay; Haberal, Ali; Akyol, Mesut Fertility and sterility // 2011;95(2):497-502	World Health Organization Quality of Life-Short Form, Turkish Version (WHOQOL-BREF TR)

<b>Comparison of scales for evaluating premenstrual symptoms in women using oral contraceptives.</b>	Coffee, Andrea L; Kuehl, Thomas J; Sulak, Patricia J Pharmacotherapy // 2008;28(5):576-583	Scott & White Daily Diary of Symptoms, and a multiple-item questionnaire, the Penn State Daily Symptom Report (DSR)
<b>Contraception and quality of life</b>	Perez E F European Journal of Contraception and Reproductive Health Care // 2010;15():216-219	SF-36, SF-12 or WHOQoL, Q-LES-Q and POMS), MDQ (Menstrual Distress Questionnaire) or the DRSP (Daily Record of Severity Problems) - ?duplicate ?talking about sec-qol (not an actual study)
<b>Contraceptive vaginal ring treatment of heavy menstrual bleeding: a randomized controlled trial with norethisterone.</b>	Abu Hashim, Hatem; Alsherbini, Waleed; Bazeed, Mohamed Contraception // 2012;85(3):246-252	HRQOL-4
<b>Conventional vs. extended-cycle oral contraceptives on the quality of sexual life: comparison between two regimens containing 3 mg drospirenone and 20 micro g ethinyl estradiol.</b>	Caruso, Salvatore; Iraci Sareri, Marco; Agnello, Carmela; Romano, Mattea; Lo Presti, Lucia; Malandrino, Chiara; Cianci, Antonio The journal of sexual medicine // 2011;8(5):1478-1485	The Short Form-36 (SF-36) validate questionnaire to assess quality of life (QoL) and the Short Personal Experience Questionnaire (SPEQ)
<b>Cycle control, quality of life and acne with two low-dose oral contraceptives containing 20 mug ethinylestradiol</b>	U.H., Winkler; H., Ferguson; , Mulders J.A.P.A. Contraception // 2004;69(6):469-476	Psychological General Well-Being Index (PGWBI) and the Profile of Mood States (POMS)



<b>Daily menstrual symptom measures in women and men using an extended version of Moos's instrument</b>	T.G.H.M., Van den Boogaard; , Bijleveld C.C.J.H. Journal of Psychosomatic Obstetrics and Gynaecology // 1988;9(2):103-110	extended version of Moos's menstrual distress questionnaire (MDQ), Form T.
<b>Depressive symptomatology and quality of life assessment among women using the levonorgestrel-releasing intrauterine system: an observational study.</b>	Tazegul Pekin, Aybike; Secilmis Kerimoglu, Ozlem; Kebapcilar, Ayse Gul; Yilmaz, Setenay Arzu; Benzer, Nilgun; Celik, Cetin Archives of gynecology and obstetrics // 2014;290(3):507-511	36-item Short-Form Health Survey (SF-36) for QoL and Beck's Depression Inventory for depressive symptoms
<b>Development and validation of an acceptability and satisfaction questionnaire for a contraceptive vaginal ring, NuvaRing.</b>	Novak, Annoesjka; de la Loge, Christine; Abetz, Linda PharmacoEconomics // 2004;22(4):245-256	The NuvaRing Acceptability Questionnaire
<b>Development and validation of the SEC-QOL questionnaire in women using contraceptive methods.</b>	Perez-Campos, Ezequiel; Duenas, Jose Luis; de la Viuda, Esther; Gomez, Maria Angeles; Lertxundi, Roberto; Sanchez-Borrego, Rafael; Canals, Ignaci; Bermejo, Rafael; Arbat, Agnes; Badia, Xavier; Perulero, Nuria; Lete, Luis Ignacio Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research // 2011;14(6):892-899	SEC-QOL
<b>Effect of a combination of ethinylestradiol 30 microg and drospirenone 3 mg on tolerance, cycle control, general well-being and fluid-related symptoms in women with premenstrual disorders requesting contraception.</b>	Borges, Lavinia E; Andrade, Rosires P; Aldrighi, Jose M; Guazelli, Cristina; Yazlle, Marta Edna H D; Isaia, Carlos F; Petracco, Alvaro; Peixoto, Fabio C; Camargos, Aroldo F Contraception // 2006;74(6):446-450	Psychological General Well-Being Index (PGWBI)
<b>Effect of an oral contraceptive containing drospirenone and ethinylestradiol on general well-being and fluid-related symptoms.</b>	Apter, D; Borsos, A; Baumgartner, W; Melis, G-B; Vexiau-Robert, D; Colligs-Hakert, A; Palmer, M; Kelly, S The European journal of contraception & reproductive health care : the official	Psychological General Well-Being Index (PGWBI)

	journal of the European Society of Contraception // 2003;8(1):37-51	
<b>Effect of an oral contraceptive containing ethinyl estradiol and drospirenone on premenstrual symptomatology and health-related quality of life.</b>	Borenstein, Jeff; Yu, Hsing-Ting; Wade, Sally; Chiou, Chiun-Fang; Rapkin, Andrea The Journal of reproductive medicine // 2003;48(2):79-85	Moos Menstrual Distress Questionnaire (MDQ) and SF-12
<b>Effect of an oral contraceptive on emotional distress, anxiety and depression of women with polycystic ovary syndrome: a prospective study.</b>	Cinar, Nese; Harmanci, Ayla; Demir, Basaran; Yildiz, Bulent O Human reproduction (Oxford, England) // 2012;27(6):1840-1845	PCOSQ, Beck Depression Inventory, Hospital Anxiety and Depression Scale
<b>Effect of Depo-Provera on depression rate in the women referring to the health center of Babol city</b>	H., Salmalian; F., Khirkhah; R., Saghebi; F.N., Amiri; M., Hajiahmadi; , Pasha H Scientific Journal of Kurdistan University of Medical Sciences // 2011;16(2):27-35	Beck
<b>Effect of hysterectomy vs medical treatment on health-related quality of life and sexual functioning: the medicine or surgery (Ms) randomized trial.</b>	Kuppermann, Miriam; Varner, R Edward; Summitt, Robert L Jr; Learman, Lee A; Ireland, Christine; Vittinghoff, Eric; Stewart, Anita L; Lin, Feng; Richter, Holly E; Showstack, Jonathan; Hulley, Stephen B; Washington, A Eugene; Group, Ms Research JAMA // 2004;291(12):1447-1455	Mental Component Summary (MCS) of the 36-Item Short-Form Health Survey (SF-36)
<b>Effect of oral contraceptives containing estradiol and norgestrel acetate or ethinyl-estradiol and chlormadinone acetate on primary dysmenorrhea.</b>	Grandi, Giovanni; Napolitano, Antonella; Xholli, Anjeza; Tirelli, Alessandra; Di Carlo, Costantino; Cagnacci, Angelo Gynecological endocrinology : the official journal of the International Society of Gynecological Endocrinology // 2015;31(10):774-778	Visual Analogue Scale (VAS) score for dysmenorrhea, Short Form-36 questionnaire

<b>Effect on quality of life of switching to combined oral contraception based on natural estrogen: an observational, multicentre, prospective phase IV study (ZOCAL Study).</b>	Lete, Inaki; de la Viuda, Esther; Perez-Campos, Ezequiel; Martinez, Maria Angeles Gomez; Sanchez-de la Rosa, Rainer; Novalbos, Jesus; Sanchez-Borrego, Rafael The European journal of contraception & reproductive health care : the official journal of the European Society of Contraception // 2016;21(4):276-284	SEC-QOL
<b>Effects of continuous versus cyclical oral contraception: a randomized controlled trial.</b>	Legro, Richard S; Pauli, Jaimey G; Kunselman, Allen R; Meadows, Juliana W; Kesner, James S; Zaino, Richard J; Demers, Laurence M; Gnatuk, Carol L; Dodson, William C The Journal of clinical endocrinology and metabolism // 2008;93(2):420-429	Moos Menstrual Distress Questionnaire
<b>Effects of low-dose combined drospirenone-ethinylestradiol on perimenstrual symptoms experienced by women with endometriosis.</b>	Tanaka, Yukiko; Mori, Taisuke; Ito, Fumitake; Koshiba, Akemi; Kusuki, Izumi; Kitawaki, Jo International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics // 2016;135(2):135-139	menstrual distress questionnaire (MDQ)
<b>Effects of oral contraceptives containing ethinylestradiol with either drospirenone or levonorgestrel on various parameters associated with well-being in healthy women: a randomized, single-blind, parallel-group, multicentre study.</b>	Kelly, Sue; Davies, Emyr; Fearn, Simon; McKinnon, Carol; Carter, Rick; Gerlinger, Christoph; Smithers, Andrew Clinical drug investigation // 2010;30(5):325-336	Menstrual Distress Questionnaire (MDQ)
<b>Effects of oral contraceptives on daily self-ratings of positive and negative affect.</b>	Oinonen, K A; Mazmanian, D Journal of psychosomatic research // 2001;51(5):647-658	Positive and Negative Affect Schedule (PANAS) and the Menstrual Distress Questionnaire (MDQ)

<b>Effects on the quality of life of a new oral contraceptive containing 30 mcg EE and 3 mg drospirenone (Yasmin)</b>	J., Bitzer; S., Tschudin; J., Meier-Burgoa; U., Armbruster; , Schwendke A Schweizerische Rundschau fur Medizin Praxis = Revue suisse de medecine Praxis // 2003;92(25-26):1177-1184	self developed questionnaire using 20 items with a 5 scale answer scheme
<b>Efficacy and safety of drospirenone-ethinylestradiol on contraception in healthy Chinese women: a multicenter randomized controlled trial.</b>	Fan, Guang-sheng; Bian, Mei-lu; Cheng, Li-nan; Cao, Xiao-ming; Huang, Zi-rong; Han, Zi-yan; Jing, Xiao-ping; Li, Jian; Wu, Shu-ying; Xiong, Cheng-liang; Xiong, Zheng-ai; Yue, Tian-fu Zhonghua fu chan ke za zhi // 2009;44(1):38-44	Moos Menstrual Distress Questionnaire
<b>Efficacy of Acupuncture versus Combined Oral Contraceptive Pill in Treatment of Moderate-to-Severe Dysmenorrhea: A Randomized Controlled Trial.</b>	Sriprasert, Intira; Suerungruang, Suparek; Athilarp, Porntip; Matanasarawoot, Anuchart; Teekachunhatean, Supanimit Evidence-based complementary and alternative medicine : eCAM // 2015;2015():735690-735690	SF-36
<b>Evaluation of a unique oral contraceptive in the treatment of premenstrual dysphoric disorder.</b>	Megivern, Deborah Journal of women's health & gender-based medicine // 2002;11(2):95-96	Beck Depression Inventory (BDI) and Profile of Mood States (PMS)
<b>Evaluation of quality of life and cost-effectiveness of definitive surgery and the levonorgestrel intrauterine system as treatment options for heavy menstrual bleeding.</b>	Adiguzel, Cevdet; Seyfettinoglu, Sevtap; Aka Satar, Deniz; Arlier, Sefa; Eskimez, Eda; Kaya, Fatma; Nazik, Hakan Turkish journal of medical sciences // 2017;47(3):789-794	SF-36
<b>Evaluation of quality of life and sexual functioning of women using levonorgestrel-releasing intrauterine contraceptive system--Mirena.</b>	Skrzypulec, Violetta; Drosdzol, Agnieszka Collegium antropologicum // 2008;32(4):1059-1068	Short Form-36 Health Survey, Female Sexual Function Index and Mell-Krat Scale
<b>Evaluation of sexual function and quality of life in Iranian women with tubal ligation: a historical cohort study.</b>	Sadatmahalleh, Sh Jahanian; Ziaei, S; Kazemnejad, A; Mohamadi, E International journal of impotence research // 2015;27(5):173-177	Short Form Health Survey (SF-12)

<b>Evaluation of the quality of life and sexual functioning of women using a 30-mug ethinyloestradiol and 3-mg drospirenone combined oral contraceptive</b>	V., Skrzypulec; , Drosdzol A European Journal of Contraception and Reproductive Health Care // 2008;13(1):49-57	Polish version of the Short Form-36 Health Survey (SF-36), Female Sexual Function Index (FSFI) and Mell-Krat Scale (SFK-K)
<b>Health status function after treatment with thermal balloon endometrial ablation and levonorgestrel intrauterine system for idiopathic menorrhagia: a randomized study.</b>	Tam, Wing Hung; Yuen, Pong Mo; Shan Ng, Doris Pui; Leung, Pui Ling; Lok, Ingrid Hung; Rogers, Michael Scott Gynecologic and obstetric investigation // 2006;62(2):84-88	SF-36
<b>Health-related quality of life changes among users of depot medroxyprogesterone acetate for contraception.</b>	Wanyonyi, Sikolia Z; Stones, William R; Sequeira, Evan Contraception // 2011;84(5):e17-22	SF-36
<b>Hormonal contraception and mental health: results of a population-based study.</b>	Toffol, E; Heikinheimo, O; Koponen, P; Luoto, R; Partonen, T Human reproduction (Oxford, England) // 2011;26(11):3085-3093	Beck Depression Inventory (BDI)], psychological well-being [(General Health Questionnaire-12 (GHQ-12))]
<b>How to measure quality of life</b>	M.A., Gomez; , Lete I European Journal of Contraception and Reproductive Health Care // 2010;15():13-13	SF-36, SF-12 or WHOQoL, specific psychiatric questionnaires (QLES- Q y POMS), specific questionnaires related to the menstrual cycle (MDQ or DRSP), sexual function questionnaires (DSFI) and psychological well-being questionnaires (BPI)

<b>Identification and validation of quality of life measures in a population of women with premalignant and malignant pathology at childbearing age.</b>	Patriciu, Achimas-Cadariu; Irimie, Alexandru; Iancu, Mihaela; Pop, Florina; Lancrajan, Ioan; Lisencu, Cosmin Journal of Cognitive and Behavioral Psychotherapies // 2013;13(2):409-420	EORTC OLQ-C30
<b>Impact of an implantable steroid contraceptive (etonogestrel-releasing implant) on quality of life and sexual function: a preliminary study.</b>	Di Carlo, Costantino; Sansone, Anna; De Rosa, Nicoletta; Gargano, Virginia; Tommaselli, Giovanni Antonio; Nappi, Carmine; Bifulco, Giuseppe Gynecological endocrinology : the official journal of the International Society of Gynecological Endocrinology // 2014;30(1):53-56	The Female Sexual Function Index (FSFI) questionnaire and the Short Form-36 (SF-36)
<b>Impact of common contraceptive methods on quality of life and sexual function in Hong Kong Chinese women.</b>	Li, Raymond H W; Lo, Sue S T; Teh, Dawn K G; Tong, Ngai-Chiu; Tsui, Michelle H Y; Cheung, Kai-Bun; Chung, Tony K H Contraception // 2004;70(6):474-482	WHOQOL questionnaire and the Derogatis Sexual Functioning Inventory (DSFI)
<b>Impact of different contraceptive methods on quality of life in rural women of the Jiangsu province in China.</b>	Zhao, Jinna; Li, Ying; Wu, Yulin; Zhou, Jian; Ba, Lei; Gu, Xiaoping; Wang, Weidong; Yao, Hui; Ren, Naixiu; Chen, Jianhong; Xu, Lianfang Contraception // 2009;80(2):180-186	Quality of Life Enjoyment and Satisfaction Questionnaire
<b>Impact of use of combined oral contraceptive pill on the quality of life of Japanese women.</b>	Matsumoto, Yasuyo; Yamabe, Shingo; Ideta, Kazuhisa; Kawabata, Masato The journal of obstetrics and gynaecology research // 2007;33(4):529-535	WHOQOL
<b>Improvement of quality of life in women using a low-dose desogestrel-containing contraceptive: results of an observational clinical evaluation.</b>	Ernst, U; Baumgartner, L; Bauer, U; Janssen, G The European journal of contraception & reproductive health care : the official journal of the European Society of Contraception // 2002;7(4):238-243	quality of life questionnaires (Q-LES-Q)
<b>Incidence of depressive symptoms in users of the oral contraceptive.</b>	Fleming, O; Seager, C P The British Journal of Psychiatry // 1978;132():431-440	Eysenck Personality Inventory

<b>Levonorgestrel intrauterine system versus medical therapy for menorrhagia.</b>	Gupta, Janesh; Kai, Joe; Middleton, Lee; Pattison, Helen; Gray, Richard; Daniels, Jane; Group, ECLIPSE Trial Collaborative The New England journal of medicine // 2013;368(2):128-137	(SF-36), version 2, the EuroQol Group 5-Dimension SelfReport Questionnaire (EQ-5D) descriptive system and the EQ-5D visual-analogue scale and The validated Sexual Activity Questionnaire measures pleasure
<b>Levonorgestrel-releasing intrauterine system versus laparoscopic supracervical hysterectomy for the treatment of heavy menstrual bleeding: a randomized study.</b>	Sesti, Francesco; Piancatelli, Raffaella; Pietropolli, Adalgisa; Ruggeri, Velia; Piccione, Emilio Journal of women's health (2002) // 2012;21(8):851-857	SF-36
<b>Levonorgestrel-releasing IUD versus copper IUD in control of dysmenorrhea, satisfaction and quality of life in women using IUD.</b>	Ramazanzadeh, Fatemeh; Tavakolianfar, Toktam; Shariat, Mamak; Purafzali Firuzabadi, Seyed Javad; Hagholahi, Fedieh Iranian journal of reproductive medicine // 2012;10(1):41-46	SF-36
<b>Low dose oral contraceptives and quality of life</b>	Ch., Egarter; M.A., Topcuoglu; M., Imhof; , Huber J Journal fur Fertilitat und Reproduktion // 1999;9(1):38-43	Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q)
<b>Medicine or Surgery (Ms): a randomized clinical trial comparing hysterectomy and medical treatment in premenopausal women with abnormal uterine bleeding.</b>	Varner, R Edward; Ireland, Christine C; Summitt, Robert L Jr; Richter, Holly E; Learman, Lee A; Vittinghoff, Eric; Kuppermann, Miriam; Washington, Eugene; Hulley, Stephen B; Group, Ms Research Controlled clinical trials // 2004;25(1):104-118	mental and physical component surveys of Short Form-36

<b>Menstrual Cycle as Focus of Study and Self-Reports of Moods and Behaviors.</b>	Englander-Golden, Paula; Whitmore, Mary R; Dienstbier, Richard A Motivation and Emotion // 1978;2(1):75-86	Menstrual Distress Questionnaire (MDQ)
<b>Menstrual cycle moods and symptoms in young, healthy women: A heuristic model.</b>	Boyle, Gregory J Multivariate Experimental Clinical Research // 2000;12(1):13-28	Eight State Questionnaire and the Menstrual Distress Questionnaire.
<b>Menstrual distress and sex-role attributes.</b>	Good, Paul R; Smith, Barry D Psychology of Women Quarterly // 1980;4(4):482-491	Moos Menstrual Distress Questionnaire) and sex-role attributes (Bem Sex-Role Inventory), short form adapted from the Taylor Manifest Anxiety Scale
<b>Mood changes in adolescents using depot-medroxyprogesterone acetate for contraception: A prospective study</b>	N., Gupta; R., O'Brien; L.J., Jacobsen; A., Davis; A., Zuckerman; S., Supran; , Kulig J Journal of Pediatric and Adolescent Gynecology // 2001;14(2):71-76	Beck Depression Inventory (BDI) and the Multiple Affect Adjective Checklist-Revised (MAACL-R)
<b>One year quality of life measured with SEC-QoL in levonorgestrel 52 mg IUS users.</b>	Cristobal, Ignacio; Lete, Luis Ignacio; Viuda, Esther de la; Perulero, Nuria; Arbat, Agnes; Canals, Ignasi Contraception // 2016;93(4):367-371	SEC-QOL
<b>Oral contraceptives and premenstrual symptoms: comparison of a 21/7 and extended regimen.</b>	Coffee, Andrea L; Kuehl, Thomas J; Willis, Sherilyn; Sulak, Patricia J American journal of obstetrics and gynecology // 2006;195(5):1311-1319	Scott and White (S&W) Mood Scale and the Penn State Daily Symptom Report (DSR17)
<b>Oral contraceptives for dysmenorrhea in adolescent girls: a randomized trial.</b>	Davis, Anne Rachel; Westhoff, Carolyn; O'Connell, Katharine; Gallagher, Nancy Obstetrics and gynecology // 2005;106(1):97-104	Moos Menstrual Distress Questionnaire
<b>Oral contraceptives: side effects and depression in adolescent girls</b>	K., O'Connell; A.R., Davis; , Kerns J Contraception // 2007;75(4):299-304	Center for Epidemiologic Studies



		Depression Scale (CES-D)
<b>ORTHO birth control satisfaction assessment tool: assessing sensitivity to change and predictors of satisfaction.</b>	Mathias, Susan D; Colwell, Hilary H; Lococo, John M; Karvois, Debra L; Pritchard, Michelle L; Friedman, Andrew J Contraception // 2006;74(4):303-308	ORTHO BC-SAT
<b>Patient acceptability and satisfaction with Lunelle(TM) monthly contraceptive injection (medroxyprogesterone acetate and estradiol cypionate injectable suspension)</b>	L.P., Shulman; M., Oleenburkey; , Willke R J Contraception // 1999;60(4):215-222	User Satisfaction Questionnaire (USQ), a Treatment Assessment Questionnaire (TAQ), and the Global Well-Being Schedule (GWB) questionnaire.
<b>Postoperative levonorgestrel-releasing intrauterine system for pelvic endometriosis-related pain: A randomized controlled trial</b>	P., Tanmahasamut; M., Rattanachaiyanont; S., Angsuwathana; K., Techatraisak; S., Indhavivadhana; , Leerasiri P Obstetrics & Gynecology // 2012(;):	Short Form-36 score
<b>Preliminary study on the effect of four-phasic estradiol valerate and dienogest (E2V/DNG) oral contraceptive on the quality of sexual life.</b>	Caruso, Salvatore; Agnello, Carmela; Romano, Mattea; Cianci, Stefano; Lo Presti, Lucia; Malandrino, Chiara; Cianci, Antonio The journal of sexual medicine // 2011;8(10):2841-2850	The SF-36 and the SPEQ questionnaires
<b>Premenstrual tension: a study using the Moos Menstrual Questionnaire.</b>	Rouse, P Journal of psychosomatic research // 1978;22(3):215-222	Moos MDS
<b>Primary dysmenorrhea treatment with a desogestrel-containing low-dose oral contraceptive</b>	S.L., Hendrix; , Alexander N J Contraception // 2002;66(6):393-399	Menstrual Distress Questionnaire (MDQ)
<b>Progestin-only contraception compared with extended combined oral contraceptive in women with migraine</b>	Morotti, Matteo; Remorgida, Valentino; Venturini, Pier Luigi; Ferrero, Simone European journal of obstetrics, gynecology, and reproductive biology // 2014;183():178-182	SF-36

<b>without aura: a retrospective pilot study.</b>		
<b>Prospectively reported symptom change across the menstrual cycle in users and non-users of oral contraceptives</b>	C., Ross; G., Coleman; , Stojanovska C Journal of Psychosomatic Obstetrics and Gynecology // 2003;24(1):15-29	modified version of the Moos Menstrual Distress Questionnaire
<b>Psychological effect of the oral contraceptive formulation containing 3 mg of drospirenone plus 30 mug of ethinyl estradiol</b>	A.M., Paoletti; S., Lello; S., Fratta; M., Orru; F., Ranuzzi; C., Sogliano; A., Concas; G., Biggio; , Melis G B Fertility and Sterility // 2004;81(3):645-651	SCL-90
<b>Quality of life and costs of levonorgestrel-releasing intrauterine system or hysterectomy in the treatment of menorrhagia: a 10-year randomized controlled trial.</b>	Heliovaara-Peippo, Satu; Hurskainen, Ritva; Teperi, Juha; Aalto, Anna-Mari; Grenman, Seija; Halmesmaki, Karoliina; Jokela, Markus; Kivela, Aarre; Tomas, Eija; Tuppurainen, Marjo; Paavonen, Jorma American journal of obstetrics and gynecology // 2013;209(6):535.e1-535.e14	The 5-Dimensional EuroQol (EQ-5D), RAND-36 Spielberger 20-Item State-Trait Anxiety Inventory, Beck Depression Inventory, McCoy Sex Scale
<b>Quality of life and general well-being after switching to an oral contraceptive containing drospirenone (Yasmin(R))</b>	J., Bitzer; I.R., Kagi; B., Frey; S., Tschudin; , Alder J Journal fur Fertilitat und Reproduktion // 2007;17(1):7-14	No full text. "five-scale questionnaire containing 22 items to investigate the impact of these positive effects on quality of life" ?validated?
<b>Quality of life in patients using oral contraception</b>	D., Driak; K., Hurt; P., Holy; B., Sehnal; O., Sottner; , Halaska M European Journal of Contraception and Reproductive Health Care // 2010;15():165-165	Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q)

<b>Quality of sexual life in hyperandrogenic women treated with an oral contraceptive containing chlormadinone acetate.</b>	Caruso, Salvatore; Rugolo, Salvatore; Agnello, Carmela; Romano, Mattea; Cianci, Antonio The journal of sexual medicine // 2009;6(12):3376-3384	The Short Personal Experience Questionnaire (SPEQ), the Short Form-36 (SF-36), and a visual analog scales questionnaires were used to assess the Qo
<b>Quality of sexual life of women on oral contraceptive continued-regimen: pilot study.</b>	Caruso, Salvatore; Malandrino, Chiara; Cicero, Carla; Ciancio, Fabio; Cariola, Maria; Cianci, Antonio The journal of sexual medicine // 2013;10(2):460-466	The Female Sexual Function Index (FSFI) and the Short Form-36 (SF-36) questionnaires
<b>Quality of sexual life of women using the contraceptive vaginal ring in extended cycles: preliminary report.</b>	Caruso, Salvatore; Cianci, Stefano; Malandrino, Chiara; Cicero, Carla; Lo Presti, Lucia; Cianci, Antonio The European journal of contraception & reproductive health care : the official journal of the European Society of Contraception // 2014;19(4):307-314	Female Sexual Function Index (FSFI) and the Short Form-36 (SF-36) The Female Sexual Distress Scale (FSDS)
<b>Randomized clinical trial of a levonorgestrel-releasing intrauterine system and a depot GnRH analogue for the treatment of chronic pelvic pain in women with endometriosis.</b>	Petta, Carlos A; Ferriani, Rui A; Abrao, Mauricio S; Hassan, Daniela; Rosa E Silva, Julio C; Podgaec, Sergio; Bahamondes, Luis Human reproduction (Oxford, England) // 2005;20(7):1993-1998	PGWBI
<b>Satisfaction and health-related quality of life in women with heavy menstrual bleeding; results from a non-interventional trial of the levonorgestrel-releasing intrauterine system or conventional medical therapy.</b>	Xu, Ling; Lee, Byung Seok; Asif, Shaheena; Kraemer, Peter; Inki, Pirjo International journal of women's health // 2014;6():547-554	menorrhagia multi-attribute scale (MMAS)

<b>Self-reported health in adolescent girls varies according to the season and its relation to medication and hormonal contraception--a descriptive study.</b>	Kristjansdottir, Jona; Olsson, Gunilla I; Sundelin, Claes; Naessen, Tord The European journal of contraception & reproductive health care : the official journal of the European Society of Contraception // 2013;18(5):343-354	SF-36 and MADRS-S.
<b>Sexual Functioning in Women Using Levonorgestrel-Releasing Intrauterine Systems as Compared to Copper Intrauterine Devices</b>	P., Enzlin; S., Weyers; D., Janssens; W., Poppe; C., Eelen; E., Pazmany; E., Elaut Journal of Sexual Medicine ;():	Beck and WHO-5
<b>Studying heterogeneity in treatment response in women with idiopathic menorrhagia treated with levonorgestrel-releasing intrauterine system (LNG-IUS): Application of innovative methods to identify differential response</b>	D.E., Stull; K., Houghton; A., Filonenko; , Wittrup-Jensen K Value in Health // 2011;14(7):A410-A410	Mental Component Summary (MCS) of the SF-36v2
<b>The effect of DHEA on mood disturbances during OC use</b>	A., Van Wijck; F., Roumen; H., Coelingh Bennink; , Zimmerman Y European Journal of Contraception and Reproductive Health Care // 2010;15():139-140	General Effect Study medication Questionnaire (GESQ), short form of the Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LESQ)
<b>The effect of hysterectomy and/or oophorectomy on sexual satisfaction</b>	G., Sozeri-Varma; N., Kalkan-Oguzhanoglu; F., Karadag; , Ozdel O Climacteric // 2011;14(2):275-281	Hamilton Depression Rating Scale, the Hamilton Anxiety Scale and the Golombok Rust Inventory of Sexual Satisfaction (GRISS)

<b>The efficacy of Implanon for the treatment of chronic pelvic pain associated with pelvic congestion: 1-year randomized controlled pilot study.</b>	Shokeir, Tarek; Amr, Mostafa; Abdelshaheed, Mahmoud Archives of gynecology and obstetrics // 2009;280(3):437-443	Hospital anxiety and depression scale (HADS), VAS, VRS
<b>The EVAPIL scale, a new tool to assess tolerance of oral contraceptives.</b>	Graesslin, Olivier; Barjot, Philippe; Hoffet, Mederic; Cohen, Daniel; Vaillant, Philippe; Clerson, Pierre Contraception // 2009;80(6):540-554	Evapil
<b>The impact of oral contraceptives on the experience of perimenstrual mood, clumsiness, food craving and other symptoms.</b>	Bancroft, John; Rennie, Dilys Journal of Psychosomatic Research // 1993;37(2):195-202	Menstrual Health Questionnaire
<b>The levonorgestrel intrauterine system (Mirena) for treatment of idiopathic menorrhagia. Assessment of quality of life and satisfaction.</b>	Lete, I; Obispo, C; Izaguirre, F; Orte, T; Rivero, B; Cornellana, M J; Bermejo, I; (SEGO), Spanish Society of Gynaecology Obstetrics The European journal of contraception & reproductive health care : the official journal of the European Society of Contraception // 2008;13(3):231-237	SF-36
<b>The levonorgestrel intrauterine system as an alternative to hysterectomy for the treatment of idiopathic menorrhagia.</b>	Goni, Alvaro Zapico; Lacruz, Ramon Lanzon; Paricio, Juan Jose Parilla; Hernandez Rivas, Francisco J Gynecological endocrinology : the official journal of the International Society of Gynecological Endocrinology // 2009;25(9):581-586	SF-36 questionnaire
<b>The ORTHO BC-SAT--A Satisfaction Questionnaire for women using hormonal contraceptives.</b>	Colwell, H H; Mathias, S D; Cimms, T A; Rothman, M; Friedman, A J; Patrick, D L Quality of Life Research: An International Journal of Quality of Life Aspects of Treatment, Care & Rehabilitation // 2006;15(10):1621-1631	ORTHO BC-SAT
<b>Treatment satisfaction with a transdermal contraceptive patch or oral contraceptives.</b>	Wan, George J; Barnowski, Christopher E; Ambegaonkar, Baishali M; Bolge, Susan C; McDonnell, Diana D Contraception // 2007;75(4):281-284	HRQL (SF-8)

<b>Use of a monophasic, low-dose oral contraceptive in relation to mental functioning.</b>	Deijen, J B; Duyn, K J; Jansen, W A; Klitsie, J W Contraception // 1992;46(4):359-367	Amsterdam Mood Questionnaire (AMQ) and the Sickness Impact Profile (SIP)
<b>Use of the levonorgestrel-releasing intrauterine system in women with hemostatic disorders.</b>	Lukes, Andrea S; Reardon, Beth; Arepally, Gowthami Fertility and sterility // 2008;90(3):673-677	Self developed - A 10-item quality-of-life questionnaire developed by Kouides (Mary M. Gooley Hemophilia Treatment Center, New York)
<b>Use of the levonorgestrel-releasing intrauterine system, quality of life and sexuality. Experience in an Italian family planning center.</b>	Bastianelli, Carlo; Farris, Manuela; Benagiano, Giuseppe Contraception // 2011;84(4):402-408	EuroQuality of Life-5D and Female Sexual Function Index questionnaires
<b>Usual medical treatments or levonorgestrel-IUS for women with heavy menstrual bleeding: long-term randomised pragmatic trial in primary care.</b>	Kai, Joe; Middleton, Lee; Daniels, Jane; Pattison, Helen; Tryposkiadis, Konstantinos; Gupta, Janesh; group, ECLIPSE trial collaborative The British journal of general practice : the journal of the Royal College of General Practitioners // 2016;66(653):e861-e870	SF-36, EQ-5D, EQ-5D visual-analogue scale
<b>Validation results of a new tool to assess Health-Related Quality of Life (HRQOL) in fertile women users of contraceptive methods</b>	E., De La Viuda; M.A., Gomez; I., Lete; J.L., Duenas; R., Lertxundi; E.P., Campos; , Borrego R S European Journal of Contraception and Reproductive Health Care // 2010;15():159-160	EuroQol-5D. SEC-QOL - full text not available.

### 6.3 *ORTHO BC-SAT*

#### 6.4 SEC-QOL

1. I have menstrual pain (pain in the lumbar area and abdomen) a few days before my period starts.
2. I feel a mild discomfort in the kidney area a few days before my period starts.
3. I feel discomfort in the ovary area during my period.
4. My breasts feel harder during my period.
5. I feel that my breasts increase in size on the days before my period starts.
6. My breasts increase in size during my period.
7. I feel more nervous and I have less patience on the days before and during the first few days of my period.
8. My legs feel more tired on the days before and during the first few days of my period.
9. On the days before and during the first few days of my period, I do not feel like doing sport or any activity that is related to sudden movement.
10. On the days before and during the first few days of my period I prefer to be more calm and to do fewer things.
11. When my period coincides with the weekend, I refrain from doing things because of physical discomfort.
12. When I have my period I am more nervous at work.
13. My sexual desire decreases during the days of my period.
14. On the days before and during the first few days of my period, I feel nervous and susceptible (I get upset about anything).
15. I worry that I may have hormonal disorders.
16. When my period comes, my performance at work is somewhat lower because of menstrual pain.
17. I worry that the birth control method I use in my sexual relations may fail.
18. During the first few days of my period, when bleeding is heavier, I refuse sexual intercourse.
19. During my period, I feel that I have less energy (everything requires me more effort).